AWARD NUMBER:
W81XWH-14-1-0613

TITLE:
Fitness and Independence after SCI: Defining Meaningful Change and Thresholds

PRINCIPAL INVESTIGATOR:
Rachel E. Cowan, Ph.D.

CONTRACTING ORGANIZATION:
University of Miami School of Medicine
1400 NW 10th Avenue, DT1007P
Miami, FL 33136-1032

REPORT DATE: OCTOBER 2017

TYPE OF REPORT:
Annual

PREPARED FOR:
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT:
Approved for Public Release;
Distribution Unlimited

The views, opinions and/or findings contained in this report are those of the author(s) and should not be construed as an official Department of the Army position, policy or decision unless so designated by other documentation.

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. **PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.**

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
October 2017	Annual	**29Sept2016 - 28Sept2017**

4. TITLE AND SUBTITLE

Fitness and Independence after SCI: Defining Meaningful Change and Thresholds

5a. CONTRACT NUMBER

5b. GRANT NUMBER
W81XWH-14-1-0613

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Rachel E. Cowan, Ph.D.
Email: rcowan@med.miami.edu

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

University of Miami School of Medicine
1400 NW 10th Avenue, DT1007P
Miami, FL 33136

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT

Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT
Quality of life after SCI/D is depends more on participation, mobility, and personal care independence than injury level/severity. Fitness is a major determinant of transfer and general ADL independence in persons with SCI/D. Fitness can prevent or delay further aging related independence losses. We propose fitness represents an underappreciated approach to meaningfully improve independence and thus QOL of people living with SCI/D, no matter their injury level, age, or injury duration. In Phase 1 we interview SCI/D clinicians and consumers to determine if the candidate variables for the clinical risk calculator could be collected clinically; identify clinical techniques to assess patients' fitness; and document factors clinicians and consumers identify as fitness-function relationship confounds. In Phase 2 we collect data on 300 persons with SCI/D describing personal characteristics, criterion fitness, clinical fitness predictors, neurological impairment, balance, and functional independence. In Phase 3 we analyze Phase 2 data and develop the CRC, a tool that clinicians and consumers to determine if low fitness is limiting transfer ability.

15. SUBJECT TERMS
Spinal Cord Injury, Fitness, Independence, Quality of Life

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESONSIBLE PERSON USAMRMC
a. REPORT	**b. ABSTRACT**	**c. THIS PAGE**	U	122	**19b. TELEPHONE NUMBER** *(include area*
Unclassified	Unclassified	Unclassified			

Standard Form 298 (Rev. 8-98)
Prescribed by ANSI Std. Z39.18

TABLE OF CONTENTS

1. **INTRODUCTION:** Narrative that briefly (one paragraph) describes the subject, purpose and scope of the research.

> This study is a three-year collaboration among the University of Miami (Miami, FL), MedStar National Rehabilitation Hospital (Washington D.C.), and George Mason University (Fairfax, VA). Our scientific objectives are to a) model the fitness-independence relationship and b) estimate fitness changes and thresholds associated with greater functional independence. Our clinical translation objective is to develop a low time burden clinical tool that calculates the probability an individual's fitness is below the transfer independence threshold. We will enroll 300 non-ambulatory persons with SCI/D, making this the largest, most comprehensive examination of the fitness-function relationship in persons with SCI. We will fill critical knowledge gaps by modeling the fitness-independence relationship and by estimating fitness gains and thresholds that support meaningful independence gains. This is the only study to date linking fitness to SCIM-III performance, data critical to strengthen future therapeutic efficacy clinical trials. Finally, our clinical translation objective will accelerate application of our results to clinical practice, thereby more quickly impacting persons with SCI.

2. **KEYWORDS:** Provide a brief list of keywords (limit to 20 words).

> Spinal cord injury, fitness, independence, SCIM-III

3. **ACCOMPLISHMENTS:** The PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction.

See next Page

What were the major goals of the project?

List the major goals of the project as stated in the approved SOW. If the application listed milestones/target dates for important activities or phases of the project, identify these dates and show actual completion dates or the percentage of completion.

GOALS	Target Completion Date (month)	Actual Completion Date (month)	% Complete
Major Task 1: Establish secure regulatory approvals and establish subawards			
Subtask 1: Secure Regulatory approval of Phase 1 & Phase 2 research protocols			
Milestone Achieved: Local IRB approval at UM, NRH, GMU	June 2014	**UM:** Phase 1, Sept 2014; Phase 2, August 2014	100
		NRH: Phase 1, Dec 2014; Phase 2, Sept 2014	
		GMU: Phase 1, not involved; Phase 2, Dec 2014	
Milestone Achieved: HRPO*** approval for all protocols and local IRB** approval through UM	Sept 2014	**UM:** Phase 1, March 2015; Phase 2, June 2015	100
		NRH: Phase 1, March 2015; Phase 2, July 2015	
		GMU: Phase 1, not involved; Phase 2, June 2015	
Subtask 2: Establish subaward agreements with NRH and GMU			
Milestone achieved: Subaward agreements completed	Sept 2014	**NRH:** Dec 2014	100
		GMU: Jan 2015	
Milestone achieved: Subaward agreements updated annually	NA	NA	NA
Major Task 2: Coordinate Study Staff for Phase 1			
Subtask 1: Hiring of Study Staff (UM only)			
Milestone achieved: UM RA-TBD hired	Oct 2014	June 2014	100
Subtask 2: Build Survey in RedCap database			
Milestone Achieved: Survey ready to launch	Oct 2014	March 2015	100
Subtask 3: Training of Phase 1 Study Staff			
Milestone Achieved: Phase 1 Research staff trained	Oct 2014	April 2015	100

Major Task 3: Phase 1 Participant Recruitment, Participant Interviews			
Subtask 1: Phase 1 semi-structured interviews and survey launch			
Milestone Achieved: Phase 1 surveys begin	Oct 2014	April 2015	100
Milestone Achieved: Phase 1 interviews begins	Oct 2014	April 2015	100
Milestone Achieved: 24 minimum SCI/D clinicians and consumers interviewed	Jan 2015	N=16 of 24 minimum interviews	67
Milestone Achieved: 100 clinician/100 consumer completed surveys	Mar 2015	N=103 of 100 consumer surveys N=5 of 100 clinician surveys	54
Major Task 4: Refine Phase 2 Data Collection			
Subtask 1: Use Phase 1 results to refine Phase 2 data collection			
Milestone Achieved: Phase 2 data collection refined	Feb 2015	November 2015	100
Milestone Achieved: Phase 2 updates are local IRB approved by UM, NRH, and GMU	Mar 2015	UM-Dec 2015, NRH-March 2016, GMU-March 2016	100
If applicable Milestone Achieved: HRPO*** approval for all protocol updates and local IRB** approval through UM	Mar 2015	HRPO approval not applicable For local, see above milestone	100
Milestone Achieved: Phase 2 electronic data management system created	Mar-Apr 2015	A complete beta version of the Electronic data management system was completed in Y3, Q4 . It was created using RedCap and designed to enable it to serve as an archive for the dataset for sharing with the broader scientific community after completion of all study milestones	80%

Major Task 5: Coordinate Study Staff for Phase 2			
Subtask 1: Assign GRA-TBD (GMU only)			
Milestone achieved: GMU GRA-TBD selected	Mar 2015	June 2014, updated Sept 2015	100
Subtask 2: Develop Manual of Procedures			
Milestone achieved: Manual of Procedures Developed	Mar 2015	Dec 2015	100
Subtask 3: Train Study Staff			
Milestone Achieved: Phase 2 Research staff trained	Mar 2015	UM-Jan 2016, NRH & GMU-April 2016	100
Milestone Achieved: Manual of Procedures updated	Mar 2015	Ongoing as needed	90
Major Task 6: Phase 2 Participant Recruitment, Enrollment, Assessment			
Subtask 1: Phase 2 execution			
Milestone Achieved: 1st participant consented and assessed	Mar 2015	UM-Jan 2016 NRH-April 2016 GMU – July 2016	100
Milestone Achieved: 300 SCI/D consumers enrolled and complete data sets entered into the electronic data management system	June 2017	N=154 of 300 completed testing N=0 entered into electronic data management system	51
Major Task 7: Phase 3 – Data Analyses			
Subtask 1: Coordinate with Sites to monitor data collection rates and data quality			
Milestone Achieved: Participant Accrual rate stays on target and target accrual is achieved (N=300)	June 2017	Not complete	51
Milestone Achieved: Extracted Data consists of 300 complete data sets that are 'clean' and ready to analyze after final quarterly audit.	June 2017	Not complete	51

Subtask 2: Data Analyses and Results Dissemination			
Milestone Achieved: Preliminary analyses of Specific Aims 1 & 2 presented at DoD sponsored meeting (some time in year 2)	Mar 2016	Not complete (PI was not requested to attend a DoD sponsored meeting)	0
Milestone Achieved: Final analyses of Specific Aims 1 & 2 submitted for publication	Sept 2017	Not complete	0
Milestone Achieved: Final analyses of Specific Aim 3 (CRC) submitted for publication	Sept 2017	Not complete	0
Milestone Achieved: Clinical Risk Calculator (CRC) made available to SCI/D clinicians and consumers (Please note the CRC cannot be made available until the corresponding publication has been published. While the submission is targeted for Q4 of year 3, the manuscript would not be published until after the performance period. This is why the timeline for this milestone extends beyond month 36)	Oct 2017- Sept 2018	Not complete	0

What was accomplished under these goals?

For this reporting period describe: 1) major activities; 2) specific objectives; 3) significant results or key outcomes, including major findings, developments, or conclusions (both positive and negative); and/or 4) other achievements. Include a discussion of stated goals not met. Description shall include pertinent data and graphs in sufficient detail to explain any significant results achieved. A succinct description of the methodology used shall be provided. As the project progresses to completion, the emphasis in reporting in this section should shift from reporting activities to reporting accomplishments.

<div style="border:1px solid">

   i.   **Major Activity 1: Phase 1 Participant Recruitment, Participant Interviews**
        Subtask: Complete Phase 1 data collection & extraction
        Specific Objectives:
- Complete interview enrollment objective
  - Year 3 Objectives:
    - Minimum of N=3 more civilian clinician interviews
    - Minimum of N=8 more military clinician interviews
  - Year 4 Objectives:
    - N≥1 more civilian clinician interview
    - N≥4 more military clinician interviews
- Complete Survey enrollment objective
  - Year 3 Objectives:
    - Minimum of N=97 more clinician surveys completed
  - Year 4 Objectives:
    - Rework the clinician survey to get feedback on the initial approach to the CRC presented by the PI internally during year 3.

        Key Outcomes:
- Year 2: No objectives completed
- Year 3: completion of N=2 civilian and N=1 military clinician interviews

        ******* continue next page *******

</div>

Discussion of Goals not met:
- Year 2 Discussion: In light of the departure of Personnel from NRH/GMU (Emily Tinsley) at the end of Y1 and the unexpected departure of Personnel from UM in Y2,Q2, the Lead PI made the decision to focus all Y2 efforts on Major Activities 2-4. Effort on this Activity will resume in Y3 and projected to be completed in Y3.

- Year 3 Discussion:
  - Year 3 goals not met include the targets for all interviews and surveys. It has been unexpectedly diffuclt to get clinicians to participate in the interviews. In general it sems that many are too busy with their clinical duties to make time to talk during their workday and are not open to talking immediately before or after their workday. We have been unable to develop a satisfactory solution for this issue. However, we will continue our recruitment efforts through the end of the EWOF.
  - With regard to the surveys, we did not recruit during year 3. Instead, the PI sought out clinicians and discussed the proposed CRC to get feedback similar to the objective of the survey. This approach led to the development of the initial CRC which was very well received. The PI feels the best use of the clinical surveys is to re-configure it to get feedback on the initial version of the CRC.

******* continue next page *******

ii. **Major Activity 2: Refine Phase 2 Data Collection**
Subtask 1: Use Phase 1 results to refine Phase 2 data collection
Specific Objectives:
- Phase 2 data collection refined (Y2, Q1)
- Phase 2 updates are local IRB approved by UM (Y2,Q2), NRH, (Y2,Q3), GMU(Y2,Q4)
- Phase 2 electronic data management system created – not achieved

Key Outcomes:
- Year 2:
    - The following assessments were added to Phase 2 collection based on Phase 1 results:
    - Documentation of other medical conditions present
    - Documentation of reported & observed contractures
    - Medication/vitamin/supplement list
    - Abdominal circumference
    - Overall pain – Basic Dataset
    - Spasticity – modified questions from SCI-SET
    - Documentation of observed spasticity
    - Motivation – General Causality Orientation Scale

- Year 3:
    - Phase 2 data management system was developed and beta tested, but not launched

Discussion of Stated Goals not met:
- Year 2 Discussion:
    - Phase 2 electronic data management system created – not achieved. This objective was not achieved due to the extended 'down time' accompanying personnel turnover at UM. We anticipate the system will be in place during Y3,Q2.
- Year 3 Discussion:
    - Phase 2 electronic data management system was created and pilot tested by PI. The PI implemented the beta system in RedCap and as each form was created, the PI completed several iterations of data entry to test each for easy of entry and missing items. These iterations were also used as a second opportunity to spot audit source data forms from each center.

ii. **Major Activity 3: Coordinate Study Staff for Phase 2**
Subtask 1: Develop Manual of Procedures
Key Outcomes:
- Manual of Procedures developed & updated as needed

Subtask 2: Train study staff
Key Outcomes:
- UM staff trained Jan 2016
- NRH/GMU staff trained April 2016

No updates needed for Year 3.

iv.   Major Activity 4: Phase 2 Participant Recruitment, Enrollment, Assessments
   Subtask 1: Phase 2 execution
   Specific Objectives:
- Enroll first participant at each site
- Enroll N=300 SCI/D consumers by the end of Y3
  - N=100 @ NRH/GMU combine
  - N=200 @ UM
- Enter N=300 data sets into electronic data management system

   Key Outcomes:
- Year 2:
  - First Participant tested at all sites by the end of Y2,Q4
  - NRH/GMU accrued N=19 & are on target to compete N=100 target by the end of Y3
  - MIA accrued N=30 & are on track to complete N=150 by the end of Y3
  - N=0 data sets were entered into the electronic data management system
- Year 3
  - Total N enrolled = 154 of N=300 target
    - NRH/GMU accrued N=20 in Y3 (N=39 total of N=100 target) & are on target to complete N=60 total by the end of Y4
  - MIA accrued N=86 in Y3 (N=115 total of N=target) & are on target to complete N=190 total
  - Final total accrual at the end of Y4 is anticipated to be ~N=250, 83% of the stated objective
  - N=0 datasets were entered into the electronic data management system

   Discussion of Goals not met:
- Year 2 Discussion:
  - MIA is accruing at the target N=10 month, but due to suspension of testing for ~6 months during a personnel turnover, will not achieve the N=200 target by the end of Y3. The target can be achieved approximately 6 months into a no cost extension.
  - Data sets were not entered into the electronic data management system because the system has not yet been developed. This objective will be completed in Y3.
- Year 3 Discussion:
  - NRH is accruing at an average rate of N=2 per month. NRH staff report lack of participant transportation as the primary reason for the low accrual rate. This cannot be overcome at this time. Future studies should budget to cover participant transportation
  - MIA is accruing at an average rate of N=6.7 month. Lack of participant transportation and cancellations secondary to health issues are the primary barriers. MIA has over N=200 screen passes. The challenge is getting them in. Funds for transportation would help.

What opportunities for training and professional development has the project provided?
If the project was not intended to provide training and professional development opportunities or there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe opportunities for training and professional development provided to anyone who worked on the project or anyone who was involved in the activities supported by the project. "Training" activities are those in which individuals with advanced professional skills and experience assist others in attaining greater proficiency. Training activities may include, for example, courses or one-on-one work with a mentor. "Professional development" activities result in increased knowledge or skill in one's area of expertise and may include workshops, conferences, seminars, study groups, and individual study. Include participation in conferences, workshops, and seminars not listed under major activities.

Year 2: Nothing to Report
Year 3: Nothing to Report

How were the results disseminated to communities of interest?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the results were disseminated to communities of interest. Include any outreach activities that were undertaken to reach members of communities who are not usually aware of these project activities, for the purpose of enhancing public understanding and increasing interest in learning and careers in science, technology, and the humanities.

Year 2: Nothing to Report
Year 3:
      A presentation based on the first N=69 with bilateral elbow extension was presented to the PI's faculty during Grand Rounds in March 2017.
      Two abstracts were presented by GMU students at the 2017 ACSM conference
      All three items are included in the Appendicies

What do you plan to do during the next reporting period to accomplish the goals?
If this is the final report, state "Nothing to Report."

Describe briefly what you plan to do during the next reporting period to accomplish the goals and objectives.

Our goals for the next reporting period fall under Major Tasks 3 and 6

Major Task 3: Phase 1 Participant Recruitment, Participant Interviews
Complete at least 1 civilian clinician interviews and at least N=4 military clinician interviews

Rework clinician survey to focus on getting feedback on prelim approach to CRC and target a minimum of N=25 clinician survey.

Major Task 6: Phase 2 Participant Recruitment, Enrollment, Assessments
Complete testing on N=250 of the Phase 2 N=300 total target accrual (83% of target)
Complete entry of 90% of collected data into the electronic data management system.

4. **IMPACT:** Describe distinctive contributions, major accomplishments, innovations, successes, or any change in practice or behavior that has come about as a result of the project relative to:

What was the impact on the development of the principal discipline(s) of the project?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how findings, results, techniques that were developed or extended, or other products from the project made an impact or are likely to make an impact on the base of knowledge, theory, and research in the principal disciplinary field(s) of the project. Summarize using language that an intelligent lay audience can understand (Scientific American style).

Year 2: Nothing to Report
Year 3: Nothing to Report

What was the impact on other disciplines?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how the findings, results, or techniques that were developed or improved, or other products from the project made an impact or are likely to make an impact on other disciplines.

Year 2: Nothing to Report
Year 3: Nothing to Report

What was the impact on technology transfer?

If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe ways in which the project made an impact, or is likely to make an impact, on commercial technology or public use, including:
- *transfer of results to entities in government or industry;*
- *instances where the research has led to the initiation of a start-up company; or*
- *adoption of new practices.*

Year 2: Nothing to Report
Year 3: Nothing to Report

What was the impact on society beyond science and technology?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe how results from the project made an impact, or are likely to make an impact, beyond the bounds of science, engineering, and the academic world on areas such as:
- *improving public knowledge, attitudes, skills, and abilities;*
- *changing behavior, practices, decision making, policies (including regulatory policies), or social actions; or*
- *improving social, economic, civic, or environmental conditions.*

Year 2: Nothing to Report
Year 3: Nothing to Report

5. **CHANGES/PROBLEMS:** The PD/PI is reminded that the recipient organization is required to obtain prior written approval from the awarding agency grants official whenever there are significant changes in the project or its direction. If not previously reported in writing, provide the following additional information or state, "Nothing to Report," if applicable:

Changes in approach and reasons for change
Describe any changes in approach during the reporting period and reasons for these changes. Remember that significant changes in objectives and scope require prior approval of the agency.

Year 2: Nothing to Report
Year 3: Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them
Describe problems or delays encountered during the reporting period and actions or plans to resolve them.

Problems and delays as presented in Year 1 annual report listed below *with updates presented in italics*

i. YEAR 1- Phase 1 is currently behind schedule due to delays in local IRB approval at all three sites and difficulty in recruiting clinicians, especially military/VA clinicians. This has resulted in a delay of phase 2 activities.

Actions taken to mitigate the delay & ensure the project is completed on time:

1. Expedite the interview transcription process. We have identified a solution that will enable us to have the interviews professionally transcribed within 72 hours of their recording. This will significantly decrease the total time required to extract data from the interviews.
    a. *Year 2 update: This has worked exceptionally well.*
    b. *Year 3 update: No update*
2. Dr. Groah has developed additional VA/military contacts to identify additional potential military participants
    a. *Year 2 update*: *This effort was delayed until Y3 to allow focus on Phase 2*
    b. *Year 3 update: This was somewhat successful.*
3. Dr. Cowan has identified several local clinicians to interview and will reach out to the local VA to identify potential additional clinicians.
    a. Year 2 update: *This effort was delayed until Y3 to allow focus on Phase 2*
    b. *Year 3 update: Local VA clinicians were too busy to participate*
4. Instead of waiting until Phase 1 is fully complete (i.e. saturation) before starting Phase 2, we will begin Phase 2 once the major themes from Phase 1 have been identified. This should allow us to begin phase 2 testing in Y2 Q1.
    a. *Year 2 update: This was implemented*
    b. *Year 3 update: not applicable*
5. Once phase 2 begins, we will implement a greater (but still achievable) monthly accrual rate.
    a. *Year 2 update: This was implemented.*
    b. *Year 3 update: Accrual rates at both centers are below target secondary to participation barriers, primarily transportation and short term health issues.*

ii. YEAR 1 - Phase 2 was projected to begin enrollment in Y1 Q3. Due to delays in Phase 1, Phase 2 will begin enrollment in Y2 Q1.

Year 2 update: Enrollment began Y2,Q2 @ UM, Y2,Q3 @ NRH, Y2,Q4 @ GMU

Year 3 update: Not applicable

Actions taken to mitigate issue:

1. UM will increase participant enrollment rate from the planned 8-9 per month in Y2 to 10 per month throughout Y2 and Y3.
    a. Year 2 update:
    b. Year 3 update: *Accrual rate at UM is below target secondary to participation barriers, primarily transportation and short term health issues.*
2. GMU & NRH will increase participant enrollment rate from the planned 1-2 per month in Y2 to 2-3 per month throughout Y2 and Y3.
    b. Year 2 update:
    c. Year 3 update: *Accrual rate at NRH is below target secondary to participation barriers, primarily transportation.*
1. We project to be caught up by the end of Y3 Q3, the original projected end of our enrollment period.
    d. We anticipate our final accrual will be 83% of our original target (N=250 of N=300).
        a.

iii. YEAR 2 - As indicated above, Phase 2 was originally projected to begin enrollment in Y1 Q3, but was delayed due to Phase 1 delays. Our primary action to mitigate the delays was to increase the proposed monthly accrual at all sites. NRH/GMU combined 'accelerated' accrual of 4-6 per month is anticipated to achieve their combined target accrual of N=100 by the end of Y3,Q4. However, UM has experienced additional Phase 2 delays due to personnel turnover. As indicated in the quarterly reports, this turnover resulted in low accrual in Q2, none in Q3, and low in Q4. However, UM met the target N=10 accrual in September, the first month post-hire and training of the new employee & expects to maintain the target each month.

> Actions taken to mitigate issue:
> 1. A no cost extension will be required to mitigate this additional delay. An accrual rate greater than the current 10 per month is not practically sustainable. Funds are available to support personnel in a no cost extension due to the personnel gap.
>   a. Year 3 update: No update.
> 2. Maintain the N=10 monthly accrual into a no cost extension, anticipating meeting the target UM N=200 accrual by month 6 or 7 of the no cost extension
>   a. Year 3 update: As stated elsewhere, accrual rates are below the target due to transportation and health barriers.

iv. YEAR 2 - Phase 3 activities will be delayed due to phase 2 delays. Phase 3 activities include analysis and manuscript submissions.

> Actions taken to mitigate issue:
> 1. A no cost extension will be required to mitigate this additional delay. Personnel effort for phase 3 will be reserved as planned for Phase 3 activities. The proposed manuscripts and clinical risk calculator development require data collection be complete.
>   a. Year 3 update: No update

YEAR 3 – New Problems have emerged. Updates are provided for all problems described in years 1 & 2.

Changes that had a significant impact on expenditures
Describe changes during the reporting period that may have had a significant impact on expenditures, for example, delays in hiring staff or favorable developments that enable meeting objectives at less cost than anticipated.

Year 2: Nothing to report.

Year 3: Cessation of GMU's funded effort after Y3, Q2 freed up funds. These funds will be available to fund UM personnel effort during the 12 month EWOF.

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Describe significant deviations, unexpected outcomes, or changes in approved protocols for the use or care of human subjects, vertebrate animals, biohazards, and/or select agents during the reporting period. If required, were these changes approved by the applicable institution committee (or equivalent) and reported to the agency? Also specify the applicable Institutional Review Board/Institutional Animal Care and Use Committee approval dates.

Significant changes in use or care of human subjects

Year 2: Nothing to Report
Year 3: We updated the allow inclusion of individuals less than 6 month post injury with written medical clearance. Implementation of this new criteria has not occurred as we are awaiting the outcome of the HRPO review

Significant changes in use or care of vertebrate animals

Not Applicable

Significant changes in use of biohazards and/or select agents

Not Applicable

6. **PRODUCTS:** List any products resulting from the project during the reporting period. If there is nothing to report under a particular item, state "Nothing to Report."

- **Publications, conference papers, and presentations**
  Report only the major publication(s) resulting from the work under this award.

  Journal publications. *List peer-reviewed articles or papers appearing in scientific, technical, or professional journals. Identify for each publication: Author(s); title; journal; volume: year; page numbers; status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  > Year 2: Nothing to Report
  > Year 3: Nothing to Report

  Books or other non-periodical, one-time publications. *Report any book, monograph, dissertation, abstract, or the like published as or in a separate publication, rather than a periodical or series. Include any significant publication in the proceedings of a one-time conference or in the report of a one-time study, commission, or the like. Identify for each one-time publication: author(s); title; editor; title of collection, if applicable; bibliographic information; year; type of publication (e.g., book, thesis or dissertation); status of publication (published; accepted, awaiting publication; submitted, under review; other); acknowledgement of federal support (yes/no).*

  > Year 2: Nothing to Report
  > Year 3: Nothing to Report

  Other publications, conference papers and presentations. *Identify any other publications, conference papers and/or presentations not reported above. Specify the status of the publication as noted above. List presentations made during the last year (international, national, local societies, military meetings, etc.). Use an asterisk (*) if presentation produced a manuscript.*

  > Year 2: Nothing to Report
  > Year 3: Report MP presentation

  Website(s) or other Internet site(s)
  List the URL for any Internet site(s) that disseminates the results of the research activities. A short description of each site should be provided. It is not necessary to include the publications already specified above in this section.

Year 2: Nothing to Report
Year 3: Nothing to Report

Technologies or techniques
Identify technologies or techniques that resulted from the research activities. Describe the technologies or techniques were shared.

Year 2: Nothing to Report
Year 3: Nothing to Report

- **Inventions, patent applications, and/or licenses**
Identify inventions, patent applications with date, and/or licenses that have resulted from the research. Submission of this information as part of an interim research performance progress report is not a substitute for any other invention reporting required under the terms and conditions of an award.

  Year 2: Nothing to Report
  Year 3: Nothing to Report

- **Other Products**
Identify any other reportable outcomes that were developed under this project. Reportable outcomes are defined as a research result that is or relates to a product, scientific advance, or research tool that makes a meaningful contribution toward the understanding, prevention, diagnosis, prognosis, treatment and /or rehabilitation of a disease, injury or condition, or to improve the quality of life. Examples include:
  - *data or databases;*
  - *physical collections;*
  - *audio or video products;*
  - *software;*
  - *models;*
  - *educational aids or curricula;*
  - *instruments or equipment;*
  - *research material (e.g., Germplasm; cell lines, DNA probes, animal models);*
  - *clinical interventions;*
  - *new business creation; and*
  - *other.*

Year 2 & 3:
  a. Data collected for Phase 1 (Surveys & Interviews) and Phase 2 (N=300 SCI participants).

  b. See appendices for Phase 1 surveys and interview scripts, and overview of Phase 2 data collected

7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

What individuals have worked on the project?
Provide the following information for: (1) PDs/PIs; and (2) each person who has worked at least one person month per year on the project during the reporting period, regardless of the source of compensation (a person month equals approximately 160 hours of effort). If information is unchanged from a previous submission, provide the name only and indicate "no change".

Example:

Name: *Mary Smith*
Project Role: *Graduate Student*
Researcher Identifier (e.g. ORCID ID): *1234567*
Nearest person month worked: *5*

Contribution to Project: *Ms. Smith has performed work in the area of combined error-control and constrained coding.*
Funding Support: *The Ford Foundation (Complete only if the funding support is provided from other than this award.)*

Site	Name	Project Role	Researcher Identifier	Nearest person month worked	Contribution to project	Funding support
MIA	Rachel Cowan	Lead PI	NA	1.2	Daily oversight, maintain IRB approvals, HRPO reports, DoD reports, ensure progress of project	NA
MIA	Christopher Fitzmaurice**	Research Associate	NA	10.0	Perform recruitment, screening, administer all	NA

					assessments	
NRH	Suzanne Groah	NRH PI	NA	1.0	PI oversight of all activities, coordinate efforts with GMU, recruit from clinics	NA
NRH	Inger Ljungberg	Research Program Manager	NA	1.0	Daily oversight, maintain IRB approvals, coordination of recruitment, testing, data storage	NA
NRH	Amanda Rounds****	Research Assistant	NA	2.0	Perform recruitment, screening, administer questionnaires	NA
GMU*	Randall Keyser	GMU PI	NA	0.3	PI oversight of all site activities, coordinate efforts with NRH.	NA
GMU*	Donal Murray	GMU PhD student	NA	1.5	For NRH, administer peak VO2, anthropometric measures, and performance assessments. For GMU, administer all assessments	NA

*GMU staff ceased funded effort during Y3, Q3 per mutual agreement as described in Y3,Q3 technical report. They remain intellectually involved. The reported effort reflects effort in Y3,Q1 and Y3,Q2.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

If the active support has changed for the PD/PI(s) or senior/key personnel, then describe what the change has been. Changes may occur, for example, if a previously active grant has closed and/or if a previously pending grant is now active. Annotate this information so it is clear what has changed from the previous submission. Submission of other support information is not necessary for pending changes or for changes in the level of effort for active support reported previously. The awarding agency may require prior written approval if a change in active other support significantly impacts the effort on the project that is the subject of the project report.

Rachel Cowan – 5% new effort as a Co-I on a NIDILRR funded grant, PI Elizabeth Felix

What other organizations were involved as partners?
If there is nothing significant to report during this reporting period, state "Nothing to Report."

Describe partner organizations – academic institutions, other nonprofits, industrial or commercial firms, state or local governments, schools or school systems, or other organizations (foreign or domestic) – that were involved with the project. Partner organizations may have provided financial or in-kind support, supplied facilities or equipment, collaborated in the research, exchanged personnel, or otherwise contributed.

Provide the following information for each partnership:
Organization Name:
Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)
- *Financial support;*
- *In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);*
- *Facilities (e.g., project staff use the partner's facilities for project activities);*
- *Collaboration (e.g., partner's staff work with project staff on the project);*
- *Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and*
- *Other.*

Organization Name	Location of Organization	Partner's contribution to the Project
Medstar National Rehabilitation Hospital	Washington, D.C.	Collaboration
George Mason University	Fairfax, VA	Other

8. **SPECIAL REPORTING REQUIREMENTS**

   COLLABORATIVE AWARDS: For collaborative awards, independent reports are required from BOTH the Initiating Principal Investigator (PI) and the Collaborating/Partnering PI. A duplicative report is acceptable; however, tasks shall be clearly marked with the responsible PI and research site. A report shall be submitted to **https://ers.amedd.army.mil** for each unique award.

   Not Applicable

QUAD CHARTS: If applicable, the Quad Chart (available on https://www.usamraa.army.mil) should be updated and submitted with attachments.

> See next page

9. **APPENDICES:** Attach all appendices that contain information that supplements, clarifies or supports the text. Examples include original copies of journal articles, reprints of manuscripts and abstracts, a curriculum vitae, patent applications, study questionnaires, and surveys, etc.

> **a.** Survey – Clinician
>
> **b.** Survey – Consumer
>
> **c.** Interview Script – Clinician
>
> **d.** Interview Script – Consumer
>
> e. Overview of Phase 2 data collected
>
> f. Presentation
>
> g. Abstracts presented at ACSM 2017

Fitness and Independence after SCI: Defining Meaningful Changes and Thresholds
SC130235/A-18535
W81XWH-14-1-0613

PI: Rachel E. Cowan, Ph.D.   **Org:** University of Miami Miller School of Medicine   **Award Amount:** $655,245

Study/Product Aims

- Specific Aim 1: To define the magnitude of fitness increase required to achieve meaningful improvement in functional independence and determine if this number varies by injury level, fitness level and injury duration.
- Specific Aim 2: To define the minimum fitness required to achieve maximal transfer independence.
- Specific Aim 3: To develop a clinical risk calculator (CRC) that allows clinicians and SCI consumers to quantify the probability that fitness is less than the minimum required to enable transfer independence.

Approach

Phase 1: Interview SCI/D clinicians and consumers to 1) determine if the candidate variables for the clinical risk calculator are or could be collected clinically; 2) determine each variable's time collection burden; 3) identify clinical techniques to assess patients' fitness; and 4) document factors clinicians and consumers identify as fitness-function relationship confounds.

Phase 2: Collect data on 300 persons with SCI/D describing personal characteristics, criterion fitness, clinical fitness predictors, neurological impairment, balance, and functional independence.

Phase 3: Analyze Phase 2 data and develop the clinical risk calculator.

Initial pass at developing CRC to predict patient fitness & map against fitness required to transfer from floor to wheelchair (N=69). X axis is fitness level. Y axis is rank order of predicted fitness levels for N=69 with triceps function. Minimum fitness required to complete floor to wheelchair transfer is 0.80W/kg. All individuals to left lack sufficient fitness. Degree of impairment is represented by G codes (e.g. CM, CL, CK, etc..) which the federal government mandates physical therapist therapists use on Medicare claim forms to document their patients function and condition.
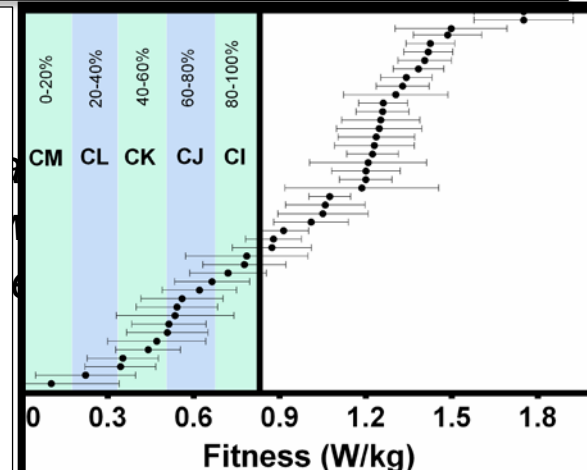
Timeline and Cost

Activities	CY	14	15	16
Phase 1 Interviews (N=9 of 8 consumers) (N=7 of 8 civilian clinicians) (N=1 of 8 military clinicians)		▮		
Phase 1 Surveys (N=101 of 100 consumer) (N=7 of 100 clinicians)		▮		
Phase 2 Data collection (N=49 of N=300) began Jan 2016			▮	
Phase 3 Analyses				▮
Estimated Budget ($K) (total costs)		$240	$201	$214

Goals/Milestones

- ☐ Phase 1: Complete min of 24 interviews
    - ✓ Complete min N=8 consumer interviews (9/8 comp)
    - ☐ Complete min N=8 civilian clinician interviews (7/8 comp)
    - ☐ Complete min N=8 military clinician interviews (1/8 comp)
- ☐ Phase 1: Complete min 200 surveys
    - ✓ Complete min N=100 consumer surveys (101/100 comp)
    - ☐ Complete min N=100 clinician surveys (7/100 comp)
- ☐ Phase 2: Enroll N=300 total (N=154/100 comp)
    - ☐ N=100 @ NRH/GMU (39/100 comp)
    - ☐ N=200 @ MIA (115/100 comp)
- ☐ Phase 3 – Complete proposed analyses

Comments/Challenges/Issues/Concerns

- Phase 2 delayed due to delay in Phase 1 and personnel turnover
- Phase 1 completion put on hold until year 4.
- Phase 2 Total accrual will be ~83% of target due to transportation and health related participation barriers

Budget Expenditure to Date: Projected: $655,245(DC+IDC); Actual:$424,596 (DC+IDC)

Survey of feasibility of clinical and community approaches to assess fitness in persons with spinal cord injury

Please complete the survey below.

Thank you!

Introduction and Background Information

Research has shown that quality of life (QOL) after Spinal Cord Injury or Disease (SCI/D) depends more on participation, mobility, and personal care independence than on absolute severity of injury.

Transfers are particularly critical to independence, with wheelchair to car, wheelchair to wheelchair, and ground to wheelchair transfers ranked by persons with SCI as skills rated in the top seven of those most essential to daily life. Fitness level is a major determinant of transfer and general ADL (Activities of Daily Living) independence in persons with SCI/D and we suggest that it represents an underappreciated approach to meaningfully improving the independence, and thus QOL, of people living with SCI/D, no matter their age, injury severity, or time since injury.

We are developing a low time burden clinical tool that will allow you to determine the likelihood that your patient's fitness level is the reason why his or her bed, toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide you information to help your patient pursue exercise and nutrition changes that could improve his or her transfer independence.

This survey is a part of a larger study that will identify the fitness levels patients with SCI/D need in order to maximize their transfer independence. The purpose of this survey is to help us determine which variables (of the many we are collecting) we should screen for inclusion in the clinical tool. In this survey we will gather information about your ability and willingness to collect certain variables; the amount of time you are willing to spend collecting each variable or set of variables; reasons why you could not or would not collect these variables; and the total amount of time you'd be willing to spend on collecting variables for inclusion in the clinical tool.

Survey results will be integrated with the results of in-depth discussions with clinicians. If you would be willing to participate in these discussions, there will be an opportunity to provide your contact information in the following pages.

Electronic Consent

Your participation in this survey is voluntary. You may choose not to participate. If you decide not to participate in this research study, you may withdraw at any time and you will not be penalized.

Student Rights
If you are a University of Miami student, your desire not to participate, or your request to withdraw from the study, will not affect your grades or other academic standings within the University.

Employee Rights
If you are an employee of the University of Miami, your decision to participate in or to withdraw from the study will not affect your employment within the University.

This phase of the research study involves completing an online survey that will take approximately 30 minutes. If you would be willing to participate in the interview phase, you will be asked for your name and contact information. This information will not be linked to your survey responses.

All electronic records from the online survey will be stored on Miami Project to Cure Paralysis Servers which are behind the University's firewall. Within the server, records will be stored in a Working Group Folder restricted to authorized study personnel.

If you have questions about this research study, please contact Rachel Cowan, PhD at 305-243-1949 or rcowan@med.miami.edu.

Selecting the "agree" button indicates that: You have read the above information You voluntarily agree to participate You are at least 18 years of age If you do not wish to participate in the research study, please decline participation by selecting the "disagree" button.

○ Agree
○ Disagree

Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

Would you be willing to participate in the interview portion of this study (approximately 1 hour long)?

○ Yes
○ No

Please provide the following information: Name: Email: Phone number: Preferred contact method (phone/email) Best day/time to call:

_____

Please answer the following 3 questions. The answers to these questions will determine your eligibility for participation in the survey.

Please indicate which degree you possess:

○ Doctor of Medicine (M.D.)
○ Doctor of Osteopathic Medicine (D.O.)
○ Registered Nurse (R.N.)
○ Physical Therapist
○ Occupational Therapist
○ Recreational Therapist
○ Other clinical degree
○ I do not have a clinical degree

Please identify your specialty:

○ Family practice
○ Physiatry
○ Urology
○ Other

Please explain

_____

How long have you been working with SCI/D patients?

○ < 1 year
○ 1-5 years
○ 6-9 years
○ 10-19 years
○ >20 years

Have you treated SCI/D patients in the previous 5 years?

○ Yes
○ No

Have you treated SCI/D patients in the previous 10 years?

○ Yes
○ No

Have you treated SCI/D patients in the previous 15 years?

○ Yes
○ No

You do not meet the inclusion criteria for this study. Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

Please answer the following questions about yourself.

In which of the following environments do you practice? (Select all that apply)

☐ Civilian clinical setting
☐ Military clinical setting
☐ Veterans Affairs clinical setting
☐ Other

Please explain.

_____

Which of the following best describes your practice environment?

○ Academic
○ Private

Gender

○ Male
○ Female

Location of practice

○ US
○ Outside of US

Select state

- ◯ Alabama
- ◯ Alaska
- ◯ Arizona
- ◯ Arkansas
- ◯ California
- ◯ Colorado
- ◯ Connecticut
- ◯ Delaware
- ◯ Florida
- ◯ Georgia
- ◯ Hawaii
- ◯ Idaho
- ◯ Illinois
- ◯ Indiana
- ◯ Iowa
- ◯ Kansas
- ◯ Kentucky
- ◯ Louisiana
- ◯ Maine
- ◯ Maryland
- ◯ Massachusetts
- ◯ Michigan
- ◯ Minnesota
- ◯ Mississippi
- ◯ Missouri
- ◯ Montana
- ◯ Nebraska
- ◯ Nevada
- ◯ New Hampshire
- ◯ New Jersey
- ◯ New Mexico
- ◯ New York
- ◯ North Carolina
- ◯ North Dakota
- ◯ Ohio
- ◯ Oklahoma
- ◯ Oregon
- ◯ Pennsylvania
- ◯ Rhode Island
- ◯ South Carolina
- ◯ South Dakota
- ◯ Tennessee
- ◯ Texas
- ◯ Utah
- ◯ Vermont
- ◯ Virginia
- ◯ Washington
- ◯ West Virginia
- ◯ Wisconsin
- ◯ Wyoming

Fill in your country

_____

Racial ethnicity

- ◯ Hispanic or Latino
- ◯ American Indian or Alaska Native
- ◯ Asian
- ◯ Black or African-American
- ◯ Native Hawaiian or Other Pacific Islander
- ◯ White
- ◯ Other
- ◯ I would prefer to not answer this question

Please fill in your racial ethnicity:

_____

REDCap

Year of birth

- ○ 1997
- ○ 1996
- ○ 1995
- ○ 1994
- ○ 1993
- ○ 1992
- ○ 1991
- ○ 1990
- ○ 1989
- ○ 1988
- ○ 1987
- ○ 1986
- ○ 1985
- ○ 1984
- ○ 1983
- ○ 1982
- ○ 1981
- ○ 1980
- ○ 1979
- ○ 1978
- ○ 1977
- ○ 1976
- ○ 1975
- ○ 1974
- ○ 1973
- ○ 1972
- ○ 1971
- ○ 1970
- ○ 1969
- ○ 1968
- ○ 1967
- ○ 1966
- ○ 1965
- ○ 1964
- ○ 1963
- ○ 1962
- ○ 1961
- ○ 1960
- ○ 1959
- ○ 1958
- ○ 1957
- ○ 1956
- ○ 1955
- ○ 1954
- ○ 1953
- ○ 1952
- ○ 1951
- ○ 1950
- ○ 1949
- ○ 1948
- ○ 1947
- ○ 1946
- ○ 1945
- ○ 1944
- ○ 1943
- ○ 1942
- ○ 1941
- ○ 1940

As a reminder, this survey will gather information about your ability and willingness to collect certain variables, the amount of time you are willing to spend collecting each variable or set of variables, reasons why you could not or would not collect these variables, and the total amount of time you'd be willing to spend on collecting variables for inclusion in the clinical tool.   We will use this information to identify a small subset of tests and questionnaires that will take the least amount of time and provide the greatest predictive power.

Please indicate which of the following information is feasible to collect in your clinic and if you would be willing to enter it into the clinical tool.

Patient's age	⚪ Yes ⚪ No
Patient's gender	⚪ Yes ⚪ No
Patient's age at SCI/D onset	⚪ Yes ⚪ No
Time post SCI/D onset	⚪ Yes ⚪ No
SCI/D etiology	⚪ Yes ⚪ No
If patient is receiving treatment for muscle spasms? (For example: prescription medication, surgical, recreational drugs, massage, acupuncture, etc.)	⚪ Yes ⚪ No
If patient can voluntarily use the muscles of his legs to help him transfer?	⚪ Yes ⚪ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?	⚪ < 30 sec ⚪ 31-60 sec ⚪ 61-90 sec ⚪ > 90
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ It would take too long ☐ It requires too much personnel ☐ I am worried about insurance reimbursements ☐ other
Please explain.	_____

Please indicate which of the following information is feasible to collect in your clinic and if you would be wiling to enter it into the clinical tool.

Patient's height : Measurement of the length of patient's body when lying down

○ Yes
○ No

Patient's weight

○ Yes
○ No

The length of each of your patient's arms (both left and right)

○ Yes
○ No

Patient's arm span (Patient holds arms out to the side. Arm span is the distance from the tip of the right middle finger, up the arm, across the chest, down the left arm to the tip of the left middle finger.)

○ Yes
○ No

Distance from the base of the back of your patient's neck (C7) to the top of his cushion as he leans forward

○ Yes
○ No

Wheelchair fit: Angle of your patient's right elbow when his or her hand is at the top center of the pushrim

○ Yes
○ No

Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?

○ < 2 min
○ 3 min
○ 4 min
○ > 5 min

For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.

☐ It would take too long
☐ It requires too much personnel
☐ I am worried about insurance reimbursements
☐ other

Please explain.

_____

Please indicate which of the following information is feasible to collect in your clinic and if you would be wiling to enter it into the clinical tool.

Primary wheelchair used (Manual, power assist, power, other)
- ◯ Yes
- ◯ No

Wheelchair manufacturer & model (Colours, Invacare/Top End, Quickie, Tilite, etc.)
- ◯ Yes
- ◯ No

Wheelchair frame type (Rigid or folding)
- ◯ Yes
- ◯ No

Front wheel size/tire type (3", 4", 5", 6", other/ Solid or Pneumatic)
- ◯ Yes
- ◯ No

Rear wheel size/tire type (24", 25", 26" / Solid or Pneumatic)
- ◯ Yes
- ◯ No

Number of years your patient has been using this wheelchair
- ◯ Yes
- ◯ No

Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?
- ◯ < 30 sec
- ◯ 31-60 sec
- ◯ 61-90 sec
- ◯ > 90

For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.
- ☐ It would take too long
- ☐ It requires too much personnel
- ☐ I am worried about insurance reimbursements
- ☐ other

Please explain.

_____

The following item is a performance-based assessment. Please read the description and indicate if it would be feasible to perform in your clinic, if you would be willing to do so and then enter the results into the tool.

6 Minute Manual Wheelchair Propulsion Test (6MPT):

The 6MPT is a fitness measure that requires the patient to complete as many laps as possible on a short course in 6 minutes. To conduct this test, you will need a hallway of at least 15 m (approximately 50 ft) long and 3 m (approximately 10 ft) wide for the testing, cones, a measuring device and a stop watch.

Including set-up, testing and evaluation and scoring, this test will take approximately 15 minutes to conduct.

Would you be willing and able to perform this assessment in your clinic?

◯ Yes
◯ No

Why not?

☐ It would take too long
☐ It requires too much personnel
☐ I am worried about insurance reimbursements
☐ I don't have enough space
☐ I don't have the necessary equipment
☐ other

Please explain.

_____

The following item is a performance-based assessment. Please read the description and indicate if it would be feasible to perform in your clinic, if you would be willing to do so and then enter the results into the tool.

Modified Functional Reach Test (mFRT):

The mFRT will measure the patient's balance. It will involve the patient reaching forward as far as he or she can without losing balance and taking a measure of how far the patient reached. The patient will have to perform this task 5 times (2 practice, 3 measured). This test requires a padded surface to sit on as this test is not performed in the wheelchair, and a ruler for measuring distance reached.

The test will take approximately 15 minutes to set-up and perform.

Would you be willing and able to perform this assessment in your clinic?

◯ Yes
◯ No

Why not?

☐ It would take too long
☐ It requires too much personnel
☐ I am worried about insurance reimbursements
☐ I don't have enough space
☐ I don't have the necessary equipment
☐ other

Please explain.

_____

The following item is a performance-based assessment. Please read the description and indicate if it would be feasible to perform in your clinic, if you would be willing to do so and then enter the results into the tool.

Aerobic Capacity Test (VO2max):

A VO2max test is a measure of an individual's aerobic capacity. It is a standard research laboratory technique for determining an individual's fitness level and requires the use of open-circuit spirometry. A metabolic cart, arm ergometer or stationary arm bike and ECG system and/or heart rate monitor is required for this test.

This test will need to be performed in an exercise/clinical laboratory and will take approximately 60 minutes to set-up and perform.

Would you be willing and able to perform this assessment in your clinic?

○ Yes
○ No

Why not?

☐ It would take too long
☐ It requires too much personnel
☐ I am worried about insurance reimbursements
☐ I don't have enough space
☐ I don't have the necessary equipment
☐ other

Please explain.

_____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Wheelchair User Shoulder Pain Index (WUSPI):

The WUSPI is a 15 item questionnaire designed to measure shoulder pain during daily activities in individuals who use wheelchairs. The patient will mark an 'x' along a line to denote where his or her level of pain falls where 'no pain' is all the way to the left and 'worst pain ever experienced' is the far right. It requires a ruler for scoring.

This questionnaire will take approximately 10 minutes to complete and score.

Would you be willing and able to administer this
questionnaire in your clinic?

◯ Yes
◯ No

Why not?

☐ It would take too long
☐ It requires too much personnel
☐ I am worried about insurance reimbursements
☐ other

Please explain.

_____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Quality of Life Basic Data Set:

The Quality of Life Basic Data Set is a questionnaire to assess your patient's level of satisfaction with life in general and specifically physical and psychological health. The patient will select a number between 0 and 10 based on how satisfied he or she feels with that aspect of his or her personal life.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing and able to administer this
questionnaire in your clinic?   ◯ Yes
                                                        ◯ No

Why not?   ☐ It would take too long
                                                        ☐ It requires too much personnel
                                                        ☐ I am worried about insurance reimbursements
                                                        ☐ other

Please explain.   _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Self-reported Mobility Disability Questionnaire:

The Self-reported Mobility Disability Questionnaire will ask the patient to rate his or her difficulty level with pushing on a level surface, performing a level transfer (wheelchair to bed) and transfers between wheelchair and the floor. The patient will select a number between 1 and 4 based on how difficult the task is to perform.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?
◯ Yes
◯ No

Why not?
☐ It would take too long
☐ It requires too much personnel
☐ I am worried about insurance reimbursements
☐ other

Please explain.
_____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Falls Concerns Scale:

The Falls Concerns Scale is a 16 item questionnaire that will ask questions regarding how concerned the patient is about falling when doing various daily activities. The patient will select a number between 1 and 4 based on the amount of concern.

This questionnaire will take approximately 10 minutes to complete.

Would you be willing and able to administer this
questionnaire in your clinic?   ◯ Yes
                                                           ◯ No

Why not?   ☐ It would take too long
                                                           ☐ It requires too much personnel
                                                           ☐ I am worried about insurance reimbursements
                                                           ☐ other

Please explain.   _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Spinal Cord Independence Measure III (SCIM-III):

The SCIM-III is a 25 item questionnaire asking about the amount of assistance or adaptation the patient needs to eat, drink, bathe, groom, get dressed, manage bladder and bowel programs, move his or her body and move around the home and community.

This questionnaire will take approximately 15 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?	◯ Yes ◯ No

Why not?	☐ It would take too long ☐ It requires too much personnel ☐ I am worried about insurance reimbursements ☐ other

Please explain.   _____

The following is related to a questionnaire. Please read the description and indicate if you would be willing to administer the questionnaire in your clinic and enter the results into the tool.

The Spinal Cord Independence Functional Index (SCI-FI):

The SCI-FI is a computer-based test consisting of four small questionnaires. Questionnaire items will focus on the patient's basic ability to move around (basic mobility); to perform self-care activities like eating, bathing, dressing, bowel and bladder routines (self-care); to use his or her hands (fine motor); and to use his or her wheelchair (wheelchair mobility).

The SCI-FI requires 15 minutes to complete.

Would you be willing and able to administer this questionnaire in your clinic?	◯ Yes ◯ No
Why not?	☐ It would take too long ☐ It requires too much personnel ☐ I am worried about insurance reimbursements ☐ other
Please explain.	_____

As a reminder, you would input a series of items into this tool and it would determine the likelihood that your patient's fitness level is the reason why his or her bed, toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide information to help your patient pursue exercise and nutrition changes that could improve his or her transfer independence.

What would be your preferred format for the consumer tool? (Select all that apply)

- ☐ Hard copy/ paper and pencil
- ☐ Online/website
- ☐ Application for mobile device
- ☐ Integrated EMR
- ☐ Other

Please explain.

_____

How much time would you be willing to spend per patient on collecting information and measurements that you typically do not collect in clinic and would be collecting solely for input into the Clinical Risk Calculator?

- ◯ < 5 min
- ◯ < 10
- ◯ < 15 min
- ◯ 15-30 min
- ◯ 31-45 min
- ◯ 46-60 min
- ◯ >60 min

Survey of feasibility of clinical and community approaches to assess fitness in persons with spinal cord injury

Please complete the survey below.

Thank you!

Introduction and Background Information

Research has shown that quality of life (QOL) after Spinal Cord Injury or Disease (SCI/D) depends more on participation, mobility, and personal care independence than on absolute severity of injury. Transfers are particularly critical to independence, with wheelchair to car, wheelchair to wheelchair, and ground to wheelchair transfers ranked by persons with SCI in the top seven skills most essential to daily life. Fitness level is a major determinant of transfer and general ADL (Activities of Daily Living) independence in persons with SCI/D and we suggest that it represents an underappreciated approach to meaningfully improving the independence, and thus QOL, of people living with SCI/D, no matter their age, injury severity, or time since injury.

We are developing an easy to use tool that will allow you to determine the likelihood that your fitness level is the reason why your toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide you information about exercise and nutrition changes that could improve your transfer independence.

This survey is a part of a larger study that will identify the fitness levels the people with SCI/D need in order to maximize their transfer independence. The purpose of this survey is to help us determine which variables (of the many we are collecting) we should screen for inclusion in this tool. In this survey we will gather information about your ability and willingness to collect certain variables; the amount of time you are willing to spend collecting each variable or set of variables; reasons why you could not or would not collect these variables; and the total amount of time you'd be willing to spend on collecting variables for inclusion in this tool.

Survey results will be integrated with the results of in-depth discussions with people with SCI/D. If you would be willing to participate in these discussions, there will be an opportunity to provide your contact information in the following pages.

Electronic Consent

Your participation in this survey is voluntary. You may choose not to participate. If you decide not to participate in this research study, you may withdraw at any time and you will not be penalized.

Student Rights
If you are a University of Miami student, your desire not to participate, or your request to withdraw from the study, will not affect your grades or other academic standings within the University.

Employee Rights
If you are an employee of the University of Miami, your decision to participate in or to withdraw from the study will not affect your employment within the University.

This phase of the research study involves completing an online survey that will take approximately 30 minutes. If you would be willing to participate in the interview phase, you will be asked for your name and contact information. This information will not be linked to your survey responses.

All electronic records from the online survey will be stored on Miami Project to Cure Paralysis Servers which are behind the University's firewall. Within the server, records will be stored in a Working Group Folder restricted to authorized study personnel.

If you have questions about this research study, please contact Rachel Cowan, PhD at 305-243-1949 or rcowan@med.miami.edu.

Selecting the "agree" button indicates that: You have read the above information You voluntarily agree to participate You are at least 18 years of age If you do not wish to participate in the research study, please decline participation by selecting the "disagree" button.

◯ Agree
◯ Disagree

Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

Would you be willing to participate in the interview portion of this study (approximately 1 hour long)?

◯ Yes
◯ No

Please provide the following information: Name: Email: Phone number: Preferred contact method (phone/email) Best day/time to call:

_____

Please answer the following 3 questions. The answers to these questions will determine your eligibility for participation in the survey.

Can you walk by yourself without support or help from braces, other assistive devices, or people?

  ◯ Yes
  ◯ No

Start with your arms fully extended at your side. Can you bend at the elbow and bring your forearm all the way up to your upper arm (like a bicep curl)?

  ◯ Yes
  ◯ No

EXCLUDING spasms, do you use the muscles in your legs to assist in transfers?

  ◯ Yes
  ◯ No

You do not meet the inclusion criteria for this study. Please select 'Next Page' below and select SUBMIT on the following page to end the survey. Thank you for your time.

REDCap

Please answer the following questions regarding your injury level and completeness.

What site on your spinal cord is injured? (Choose 1 from drop-down menu)	○ C1 ○ C2 ○ C3 ○ C4 ○ C5 ○ C6 ○ C7 ○ C8 ○ T1 ○ T2 ○ T3 ○ T4 ○ T5 ○ T6 ○ T7 ○ T8 ○ T9 ○ T10 ○ T11 ○ T12 ○ L1 ○ L2 ○ L3 ○ L4 ○ L5 ○ Sacral
Can you feel touch in the anal area?	○ Yes ○ No
Can you feel light touch below your lesion level?	○ Yes ○ No
Can you feel the difference between sharp and dull below your lesion level?	○ Yes ○ No
Can you lift your legs against gravity?	○ Yes ○ No
Can you voluntarily tighten the anal sphincter	○ Yes ○ No

Please answer the following questions about yourself.

Gender   ◯ Male
                                           ◯ Female

Location   ◯ US
                                           ◯ Outside of US

Select state   ◯ Alabama
                                           ◯ Alaska
                                           ◯ Arizona
                                           ◯ Arkansas
                                           ◯ California
                                           ◯ Colorado
                                           ◯ Connecticut
                                           ◯ Delaware
                                           ◯ Florida
                                           ◯ Georgia
                                           ◯ Hawaii
                                           ◯ Idaho
                                           ◯ Illinois
                                           ◯ Indiana
                                           ◯ Iowa
                                           ◯ Kansas
                                           ◯ Kentucky
                                           ◯ Louisiana
                                           ◯ Maine
                                           ◯ Maryland
                                           ◯ Massachusetts
                                           ◯ Michigan
                                           ◯ Minnesota
                                           ◯ Mississippi
                                           ◯ Missouri
                                           ◯ Montana
                                           ◯ Nebraska
                                           ◯ Nevada
                                           ◯ New Hampshire
                                           ◯ New Jersey
                                           ◯ New Mexico
                                           ◯ New York
                                           ◯ North Carolina
                                           ◯ North Dakota
                                           ◯ Ohio
                                           ◯ Oklahoma
                                           ◯ Oregon
                                           ◯ Pennsylvania
                                           ◯ Rhode Island
                                           ◯ South Carolina
                                           ◯ South Dakota
                                           ◯ Tennessee
                                           ◯ Texas
                                           ◯ Utah
                                           ◯ Vermont
                                           ◯ Virginia
                                           ◯ Washington
                                           ◯ West Virginia
                                           ◯ Wisconsin
                                           ◯ Wyoming

Fill in your country   _____

Racial ethnicity

○ Hispanic or Latino
○ American Indian or Alaska Native
○ Asian
○ Black or African-American
○ Native Hawaiian or Other Pacific Islander
○ White
○ I prefer to not provide this information
○ Other

Please fill in your racial ethnicity:

_____

Year of birth

○ 1997
○ 1996
○ 1995
○ 1994
○ 1993
○ 1992
○ 1991
○ 1990
○ 1989
○ 1988
○ 1987
○ 1986
○ 1985
○ 1984
○ 1983
○ 1982
○ 1981
○ 1980
○ 1979
○ 1978
○ 1977
○ 1976
○ 1975
○ 1974
○ 1973
○ 1972
○ 1971
○ 1970
○ 1969
○ 1968
○ 1967
○ 1966
○ 1965
○ 1964
○ 1963
○ 1962
○ 1961
○ 1960
○ 1959
○ 1958
○ 1957
○ 1956
○ 1955
○ 1954
○ 1953
○ 1952
○ 1951
○ 1950
○ 1949
○ 1948
○ 1947
○ 1946
○ 1945
○ 1944
○ 1943
○ 1942
○ 1941
○ 1940

Year of injury

○ 2015
○ 2014
○ 2013
○ 2012
○ 2011
○ 2010
○ 2009
○ 2008
○ 2007
○ 2006
○ 2005
○ 2004
○ 2003
○ 2002
○ 2001
○ 2000
○ 1999
○ 1998
○ 1997
○ 1996
○ 1995
○ 1994
○ 1993
○ 1992
○ 1991
○ 1990
○ 1989
○ 1988
○ 1987
○ 1986
○ 1985
○ 1984
○ 1983
○ 1982
○ 1981
○ 1980
○ 1979
○ 1978
○ 1977
○ 1976
○ 1975
○ 1974
○ 1973
○ 1972
○ 1971
○ 1970
○ 1969
○ 1968
○ 1967
○ 1966
○ 1965
○ 1964
○ 1963
○ 1962
○ 1961
○ 1960
○ 1959
○ 1958
○ 1957
○ 1956
○ 1955
○ 1954
○ 1953
○ 1952
○ 1951
○ 1950
○ 1949
○ 1948
○ 1947
○ 1946

- ○ 1945
- ○ 1944
- ○ 1943
- ○ 1942
- ○ 1941
- ○ 1940

The following questions are related to the cause of your injury. When a question is presented, please select the option that best describes the cause of your injury. It may appear repetitive; however, each question provides unique information that we need.

Were you participating in a sporting activity (professional, recreational, or leisure) when you were injured? (For example, swimming, diving, horseback riding, biking, etc.)

◯ Yes
◯ No

Please select the sporting activity

◯ Diving (into pool, ocean, lake, etc)
◯ Swimming
◯ Surfing
◯ Motocross/dirt bike riding
◯ Cycling
◯ Gymnastics
◯ Equestrian sports (riding or racing)
◯ Other

Other

_____

Did your injury occur as the result of an assault, attack, or act of violence? (For example, gunshot, stab wound, hit by a blunt object, etc.)

◯ Yes
◯ No

Please select from the following

◯ Gunshot
◯ Stab wound
◯ Hit with blunt object
◯ Explosion
◯ Other

Other

_____

Were you in, on, or using a vehicle of any sort when you were injured (for example, a car, boat, bicycle, motorcycle, etc.)?

◯ Yes
◯ No

Please select the vehicle

◯ Car
◯ Truck
◯ ATV
◯ Motorcycle
◯ Bicycle
◯ Boat
◯ Aircraft
◯ Other

Other

_____

Was your injury the result of a fall? (For example, falling down stairs, out of a window, after a trip or slip, etc.)

◯ Yes
◯ No

Please select from the following

◯ From height or level ground
◯ Trip over an object
◯ Slipping on wet surface
◯ Other

Other

_____

It appears the cause of your SCI/D did not fall into one of the core classifications. Can you please briefly describe the cause of your SCI/D?

_____

www.projectredcap.org

REDCap

Highest level of education completed

◯ Some high school
◯ High school degree
◯ Some college
◯ College degree
◯ Some graduate classes
◯ Graduate degree

Current work status

◯ Employed, full-time (> 40 hours per week)
◯ Employed, part-time (< 40 hours per week)
◯ Unemployed
◯ Student
◯ Volunteer/Other
◯ Homemaker
◯ Retired

Current marital status

◯ Married
◯ Separated
◯ Divorced
◯ Widowed
◯ Single; not in a long-term relationship
◯ Single; in a long-term relationship but not married

Annual household income

◯ Less than $7,500
◯ $7,500 - $15,499
◯ $15,500 - $24,999
◯ $25,000 - $49,999
◯ More than $50,000

REDCap

The following section describes information and measurements that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

If you answer "yes" to both questions, you will answer "yes" on the survey. Otherwise, you will answer "no".

Age
○ Yes
○ No

Gender
○ Yes
○ No

Age when SCI/D occurred
○ Yes
○ No

How long ago did SCI/D occur
○ Yes
○ No

Cause of SCI/D
○ Yes
○ No

If you are receiving treatment for muscle spasms?
(For example: prescription medication, surgical,
recreational drugs, massage, acupuncture, etc.)
○ Yes
○ No

If you can voluntarily use the muscles of your legs
to help you transfer?
○ Yes
○ No

Assuming you were both willing and able to collect
ALL of the above information and enter it into the
tool, what is the maximum amount of time would you be
willing to spend doing so?
○ < 30 sec
○ 31-60 sec
○ 61-90 sec
○ > 90 sec

For the items that you selected 'no', please select
all of the reasons why you would not be wiling to
collect these items.
☐ I don't remember or know this information
☐ I don't understand what information you are asking
   for
☐ It would take too long to find the information
☐ I would not want to share this piece of information
☐ other

Please explain.
_____

www.projectredcap.org
REDCap

The following section describes information and measurements that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

If you answer "yes" to both questions, you will answer "yes" on the survey. Otherwise, you will answer "no".

Height : Measurement of the length of your body when lying down	◯ Yes ◯ No
Your weight	◯ Yes ◯ No
The length of each of your arms (both left and right)	◯ Yes ◯ No
Your arm span (If you hold your arms out to the side, this is the distance from the tip of your right middle finger, up your arm, across your chest, down your left arm to the tip of your left middle finger tip.)	◯ Yes ◯ No
Distance from the base of the back of your neck (C7) to the top of your cushion as you lean forward	◯ Yes ◯ No
Wheelchair fit: Angle of your right elbow when your hand is at the top center of the pushrim	◯ Yes ◯ No
Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?	◯ < 2 min ◯ 3 min ◯ 4 min ◯ > 5 min
For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.	☐ I don't remember or know this information ☐ I don't understand what information you are asking for ☐ It would take too long to find the information ☐ I would not want to share this piece of information ☐ I would not be willing or able to find someone to help me collect the information ☐ I don't know where I could get weighed ☐ other

Please explain.   _____

www.projectredcap.org   **REDCap**

The following section describes information and measurements that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

If you answer "yes" to both questions, you will answer "yes" on the survey. Otherwise, you will answer "no".

Primary wheelchair used (Manual, power assist, power, other)	○ Yes ○ No
Wheelchair manufacturer & model (Colours, Invacare/Top End, Quickie, Tilite, etc.)	○ Yes ○ No
Wheelchair frame type (Rigid or folding)	○ Yes ○ No
Front wheel size/tire type (3", 4", 5", 6", other/ Solid or Pneumatic)	○ Yes ○ No
Rear wheel size/tire type (24", 25", 26" / Solid or Pneumatic)	○ Yes ○ No
Number of years you have been using this wheelchair	○ Yes ○ No

Assuming you were both willing and able to collect ALL of the above information and enter it into the tool, how much time would you be willing to spend doing so?

○ < 30 sec
○ 31-60 sec
○ 61-90 sec
○ > 90 sec

For the items that you selected 'no', please select all of the reasons why you would not be wiling to collect these items.

☐ I don't remember or know this information
☐ I don't understand what information you are asking for
☐ It would take too long to find the information
☐ I would not want to share this piece of information
☐ I would not be willing or able to find someone to help me collect the information
☐ I don't know how to find or collect the information
☐ other

Please explain.

_____

REDCap

The following section describes a performance-based physical assessment that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

6 Minute Manual Wheelchair Propulsion Test (6MPT):

The 6MPT is a fitness measure that requires you to manually propel your wheelchair and complete as many laps as possible on a short course in 6 minutes. To conduct this test, you will need a hallway of at least 15 m (approximately 50 ft) long and 3 m (approximately 10 ft) wide, as well as cones, a yardstick and a stop watch.

Including set-up, testing and evaluation and scoring, this test will take approximately 15 minutes to conduct.

Would you be willing and able to collect this information?	◯ Yes ◯ No
Why not?	☐ I don't remember or know this information ☐ I don't understand what information you are asking for ☐ It would take too long ☐ I would not want to share this piece of information ☐ I would not be willing or able to find someone to help me collect the information ☐ I don't know how to find or collect the information ☐ other
Please explain.	_____

The following section describes a performance-based physical assessment that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

Modified Functional Reach Test (mFRT):

The mFRT will measure your balance. It will involve you reaching forward as far as you can without losing your balance and taking a measure of how far you reached. You will have to practice this task twice and record your measurements 3 more times. You will need a padded surface to sit on as this test is not performed in your wheelchair, and a ruler for measuring distance reached.

The test will take approximately 15 minutes to set-up and perform.

Would you be willing and able to collect this information?	◯ Yes ◯ No

Why not?	☐ I don't remember or know this information
	☐ I don't understand what information you are asking for
	☐ It would take too long
	☐ I would not want to share this piece of information
	☐ I would not be willing or able to find someone to help me collect the information
	☐ I don't know how to find or collect the information
	☐ other

Please explain.   _____

REDCap

The following section describes a performance-based physical assessment that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

Aerobic Capacity Test (VO2max):

A VO2max test is a measure of an individual's aerobic capacity. It is a standard research laboratory technique for determining an individual's fitness level and requires the use of open-circuit spirometry. A metabolic cart, arm ergometer or stationary arm bike and ECG system and/or heart rate monitor is required for this test. This test will need to be performed in an exercise/clinical laboratory and may require that you pay an out of pocket fee.

This test will take approximately 60 minutes to set-up and perform.

Would you be willing and able to collect this information?	◯ Yes ◯ No

Why not?

- ☐ I don't remember or know this information
- ☐ I don't understand what information you are asking for
- ☐ It would take too long
- ☐ I would not want to share this piece of information
- ☐ I would not be willing or able to find someone to help me collect the information
- ☐ I don't know how to find or collect the information
- ☐ I'm concerned about the potential cost of this test
- ☐ other

Please explain.   _____

www.projectredcap.org   **REDCap**

The following section describes questionnaires that we would use in the consumer tool.

Please read each item and think about the following:

Is it realistic for you to collect each item?

Are you willing to collect each item?

The Wheelchair User Shoulder Pain Index (WUSPI):

The WUSPI is a 15 item questionnaire designed to measure shoulder pain during daily activities in individuals who use wheelchairs. You will mark an 'x' along a line to denote where your level of pain falls; where 'no pain' is all the way to the left and 'worst pain ever experienced' is the far right. It requires a ruler for scoring.

This questionnaire will take approximately 10 minutes to complete and score.

Would you be willing to complete this questionnaire?   ◯ Yes
                                                              ◯ No

Why not?   ☐ It would take too long
                                                              ☐ I don't want to share this information
                                                              ☐ other

Please explain.   _____

The Quality of Life Basic Data Set:

The Quality of Life Basic Data Set is a questionnaire to assess an individual's level of satisfaction with life in general and specifically, physical and psychological health. You will select a number between 0 and 10 based on how satisfied you feel with that aspect of your personal life.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing to complete this questionnaire?   ◯ Yes
                                                              ◯ No

Why not?   ☐ It would take too long
                                                              ☐ I don't want to share this information
                                                              ☐ other

Please explain.   _____

The Self-reported Mobility Disability Questionnaire:

The Self-reported Mobility Disability Questionnaire will ask you to rate your difficulty level with pushing on a level surface, performing a level transfer (wheelchair to bed) and transfers between wheelchair and the floor. You will select a number between 1 and 4 based on how difficult the task is for you to perform.

This questionnaire will take approximately 5 minutes to complete.

Would you be willing to complete this questionnaire?   ◯ Yes
                                                              ◯ No

Why not?   ☐ It would take too long
                                                              ☐ I don't want to share this information
                                                              ☐ other

Please explain.   _____

The following section describes questionnaires that we would use in the consumer tool.

Please read each item and think about the following:
Is it realistic for you to collect each item?
Are you willing to collect each item?

The Falls Concerns Scale:

The Falls Concerns Scale is a 16 item questionnaire that will ask questions regarding how concerned you are about falling when doing various daily activities. You will select a number between 1 and 4 based on the amount of concern.

This questionnaire will take approximately 10 minutes to complete.

Would you be willing to complete this questionnaire?   ○ Yes
                                                         ○ No

Why not?   ☐ It would take too long
                                            ☐ I don't want to share this information
                                            ☐ other

Please explain.   _____

The Spinal Cord Independence Measure III (SCIM-III):

The SCIM-III is a 25 item questionnaire asking about the amount of assistance or adaptation you need to eat, drink, bathe, groom, get dressed, manage bladder and bowel programs, move your body (transfers) and move around the home and community.

This questionnaire will take approximately 15 minutes to complete.

Would you be willing to complete this questionnaire?   ○ Yes
                                                         ○ No

Why not?   ☐ It would take too long
                                            ☐ I don't want to share this information
                                            ☐ other

Please explain.   _____

The Spinal Cord Independence Functional Index (SCI-FI):

The SCI-FI is a computer-based test consisting of four small questionnaires. Questionnaire items will focus on your basic ability to move around (basic mobility); to perform self-care activities like eating, bathing, dressing, bowel and bladder routines (self-care); to use your hands (fine motor); and to use your wheelchair (wheelchair mobility).

The SCI-FI requires 15 minutes to complete.

Would you be willing to complete this questionnaire?   ○ Yes
                                                         ○ No

Why not?   ☐ It would take too long
                                            ☐ I don't want to share this information
                                            ☐ other

Please explain.   _____

REDCap

As a reminder, you would input a series of items into this tool and it would determine the likelihood that your fitness level is the reason why your bed, toilet-tub, or car transfers are not as independent or as easy as possible. This tool will provide information to help you pursue exercise and nutrition changes that could improve your transfer independence.

What would be your preferred format for the consumer tool? (Select all that apply)

☐ Hard copy/ paper and pencil
☐ Online/website
☐ Application for mobile device
☐ Other

Please explain.

_____

IRB Protocol #20140397

Clinician Interview Script

This interview is designed to take place immediately following the participant's verbal consent to participate in the study. The script below represents an initial point of departure. As each participant is interviewed, the researcher will apply what she has learned in the course of the interview with subsequent participants. The interview should take about 60 minutes, but could last up to 90 minutes.

Interviewer: This conversation is the first phase of a larger study. The core purpose of the larger study is to quantify the relationship between fitness and ADL function in non-ambulatory persons with SCI. To help translate our findings to clinical practice, we will develop a clinical risk calculator. This risk calculator will quantify the link between a patient's ADL function and their fitness level using information that clinicians can collect and generate output to help guide care.

The purpose of this conversation is twofold. First, your input will help shape the data we collect in the larger study to help ensure we are measuring variables that are related to the fitness-ADL function relationship. Second, your input will shape the output of the clinical risk calculator to make it as useful to your clinical efforts as possible.

Eligibility verification

Before we get to the heart of the interview, I'll need to collect a few pieces of information about you and your clinical environment. The purpose of this information is to ensure you qualify to participate in this interview and ensure we interview clinicians of different genders, professions (such a doctors, therapists, and nurses), and practice environments. We'll move through this part quickly.

1. What clinical degree(s) do you possess? [If none, end interview, person does not qualify]

2. How long have you been working with SCI/D patients? [If less than 5 years, end interview, person does not qualify]

3. Are you currently treating SCI/D patients? [If no] Have you treated SCI/D patients within the last 5 years? [If no, end interview, person does not qualify]

Demographic Information

4. Would you describe your practice environment as civilian, veterans' administration, other military, or something else? [If civilian]

   a. Would you describe you practice environment as academic, private, or both?

   b. What percentages of your practice is inpatient vs. outpatient?

   c. Is your practice in the United States?

      i. [If yes] What state?

      ii. [If no] What country?

   d. Would you describe your practice location as urban, suburban, or rural?

5. What is your gender?

6. What is your race and ethnicity?

Initial Probes:

Okay, now that we've finished the basic information, we'll start on the heart of the interview.

<mark>[First Question]</mark>

1. What patient centered symptoms or characteristics affect a patient's ability to perform various types of transfers, such as bed, shower, toilet, car and ground transfers?

    a. Items to probe about –

        i. motor impairment - x

        ii. pain (in general) - x

            1. pain (musculoskeletal)

            2. pain (neuropathic)

            3. pain (back, hands, shoulder, neck,)

        iii. spasticity, - x

        iv. endurance - x

        v. weight

        vi. motivation

            1. risk

        vii. problem solving

        viii. upper extremity strength

        ix. balance

        x. body type – arm length, weight distribution

        xi. technique

        xii. contracture

    b. Do you regularly measure any of these factors during clinic?

        i. Items to probe about

            1. Motor impairment –

            2. Strength – manual muscle test

            3. Spasticity – Ashworth/modified

            4. Pain –

            5. Motivation

                a. How do you assess motivation?

            6. Problem solving

                a. How do you assess motivation?

            7. Weight

            8. Anxiety – fall concern at different part of transfer

2. Do you in any way assess your patient's fitness during clinic visits?

3. If we could give you data that linked your patient's fitness level to ADL/IADL difficulties, could this information help you better direct their care?

    a. [If yes] How so?

    b. Do you think we need to create different reports for different practice domains (e.g. OT vs. PT)

4. If we could give you data that showed your patient's fitness was less than the amount required to support a desired functional level and if we provided nutritional and exercise conditioning treatment options, would you be willing and able to use the information to pursue these treatment options?

    a. What format would make the result most useful to you? [For example – graphs, text, treatment options, prescription templates]

    b. What format would be most useful for inclusion in your patient's medical record?

    c. How do you see communication of these data to your patients being implemented into your daily practice?

    d. Would it be helpful to link treatment options to CPT codes? (CPT: Current Procedural Terminology)

5. If we could provide data linking fitness and function in a manner that improved your ability to care for your patients, how much time would you be willing to spend collecting this data?

    a. What barriers would prevent you from collecting this data?

    b. How do you see collection of this data implemented in your daily practice?

    c. Would it be helpful to link the assessments needed to CPT codes?

Consumer Interview Script

This interview is designed to take place immediately following the participant's verbal consent to participate in the study. The script below represents an initial point of departure. As each participant is interviewed, the researcher will apply what she has learned in the course of the interview with subsequent participants. The interview should take about 60 minutes, but could last up to 90 minutes.

Interviewer: This conversation is the second part of the first phase of a larger study. The core purpose of the larger study is to quantify the relationship between fitness and independence in daily activities in non-ambulatory persons with spinal cord injury. To help our results more quickly help people with spinal cord injury we want to develop a tool for SCI/D consumers that generates a report showing how their fitness level was related to their ability to perform daily activities like dressing, bathing, transferring, or pushing a chair; how their your fitness level was less than what was needed for them to easily complete a transfer they wanted or needed to perform; and provided diet and exercise suggestions to improve transfer performance.

This conversation has two purposes. First, your input will help shape the information we collect in the larger study to help ensure we are measuring items that affect the relationship between fitness and performance of daily activities like bathing, dressing, and transfers. Second, your input will help make the consumer tool user friendly and shape the report it generates so it is as helpful as possible to people with SCI.

Eligibility verification

Before we get to the heart of the interview, I'll need to collect a few pieces of information about you. The purpose of this information is to ensure you qualify to participate in this interview and ensure we interview people of different genders, ages, injury levels, injury durations, and education levels. We'll move through this part quickly.

1. How old are you? [If <18, end interview, person does not qualify]

2. Have you had your SCI/D for at least 6 months? [If no, end interview, person does not qualify]

3. What was the cause of your injury? [If cause is a progressive disease end interview, person does not qualify]

4. Are you able to walk, stand, or lift your legs against gravity? [If yes, end interview, person does not qualify]

5. Can you bend both elbows against gravity? [If no, end interview, person does not qualify]

6. Can you actively use your leg muscles to help transfer? [If yes, end interview, person does not qualify]

Demographic Information

7. What is your gender?

8. What is your race/ethnicity?

9. What is your injury level?

10. How long have you been injured?

11. Did you attend college?

   a. [If yes] What degrees have you earned?

   b. [If none] How long did you attend college?

      i. [If no to attend college] Did you complete high school or get your GED?

      ii. [If no] What was the highest grade you completed?

Initial Probes:

Okay, now that we've finished the basic information, we'll start on the heart of the interview.

[First Question]

1. What types of transfers do you perform on a daily basis?

   a. About how many transfers do you perform each day?

      i. Probe about (get info about if they do these & about the

         1. Toilet transfers (toilet chair vs directly onto the toilet)

2. Shower/tub transfers

    a. shower chair vs bench

    b. roll into shower vs transfer into

3. Car/vehicle transfers (as driver or passenger)

    a. [If drives]

        i. Daily driver make & model

        ii. [for non-ramp vehicles] – transfer height

        iii. [for vehicles with ramp] – transfer yes/no

            1. [If yes] – describe transfer

4. Ground transfers

    a. Can they transfer from ground to chair?

    b. If yes,

        i. Last time performed

        ii. Description (i.e. do they use another object to help)

b. Is there any transfer you cannot perform that you would like to?

c. Are there any transfers that you would like to be able to perform easier or faster?

<mark>[Second question]</mark>

2. ~~Besides affecting which muscles work, is there anything about you, your health, or your spinal cord injury that has ever affected your ability to perform bed, shower, toilet, car, ground, or any other type of transfer?~~

Can you think of anything that affects your ability to do transfers?

    [examples to probe for –

        pain [shoulder, hand, back (lower)],

        spasticity,

fatigue,

balance,

technique/positioning

weight

    a. Do these items have the same amount of impact?

3. In your opinion does fitness level affect a person's ability to perform daily activities, including activities like dressing, bathing, transferring, or pushing a wheelchair?

    a. Do you think fitness has a big or little effect on these activities?

4. Is there anything you do or experience that lets you know if your fitness is getting better or worse?

    a. [If an example is needed]

        i. [For example, I have a spinal cord injury and use a manual wheelchair. When my transfers start getting harder or easier, I know either my fitness level or weight has changed].

5. If we could give you a report that showed how your fitness level was related to your ability to perform daily activities would this report be useful to you?

    a. [if examples are needed: like dressing, bathing, transferring, or pushing a chair]

    b. [If yes] Can you give us ideas about how you might use the information in the report?

6. If we could give you a report that showed you that your fitness was less than what was needed for you to easily complete a transfer that you wanted or needed to perform, and if we provided diet and exercise suggestions that could improve your transfer abilities, would you be willing and able to use the report and suggestions to change your diet and exercise habit?

   a. How could we present the information in the report to make it as useful to you as possible?

7. If we could provide a report that described how your fitness level is affecting your ability to perform daily activities in a manner that you found very useful, how much time would you be willing to spend collecting all the information needed to generate that description?

   a. Would you be willing to complete several questionnaires?

      i. How long would you be willing to spend a single questionnaires?

   b. Would you be willing to complete several performance-based assessments?

      i. Do you use a manual wheelchair? [If no, skip to next question] [If yes]

         1. Would you be willing to perform a test that requires you to push your manual wheelchair up and down a hall or basketball court as many times as possible in 6 minutes?

2. Would you be able to obtain access to a hallway or other space that is at least 50 ft long and 10 ft wide (50 ft is approximately 5 car lengths)? [If no, ask if they could find an indoor basketball court to use]

3. Would you be able to find someone who is willing keep time for the test and count the number of laps you can complete?

   a. Would you be willing to spend up to 15 minutes on this assessment?

ii. Would you be willing to test your balance seated on a padded surface with your feet on the floor?

   1. Would you be able to find someone to measure how far forward you could reach while seated on this surface?

   2. Would you be willing to spend up to 15 minutes on this assessment?

iii. Would you be willing to complete a test that requires you to use a stationary arm bike and exercise until you are exhausted?

   1. This would have to take place in an exercise laboratory or doctor's office; would you know any place where you could have a test like this done?

   2. Would you be willing to pay for this test?

      a. [If yes] How much would you be willing to pay?

[Eight Question]

8. Finally, would you prefer to get this report from a health care provider, like a Doctor or Physical Therapist, or would you prefer to be able to get this report on your own like from the web or by using an app?

   a. If on own or healthcare provider, why? (added 06/17/2015)

Non-inclusive list of data collected for phase 2.

No.	Measure	Description
Personal and Wheelchair Characteristics		
	Gender	M or F
	Spasticity treatment in last 4 weeks	Y or N
	Use of legs during transfer	Y or N
	Age when injured	Yrs.
	Injury Level	Self-Report
	Primary wheelchair	Manual, power assist, power, other
	Weight	Weight of user (kg) – weight of chair (kg)
	Weight of wheelchair	kg
	Height	Supine body length (cm)
	Arm span	cm
	Arm length	L and R (cm)
	C7 to cushion top distance	cm
	Abdominal circumference	cm
	Medications, supplements and/or vitamins currently taking	List
	Additional medical conditions identified by participants doctor	Mark all that apply from list of comorbidities.
	Indicate joint contractures/joints with limited ROM	Identify Left or Right and specific joint.
	Wheelchair Manufacturer	Choose one: Colours, Invacare/Top End, Quickie, Tilite, Other
	Wheelchair Model	Text box to fill in
	Wheelchair frame type	Rigid or Folding
	If (above) = rigid; wheelchair frame shape	Cantilevered or Box
	Rear wheel radius	24", 25", 26", other
	Rear wheel tire type	Solid or Pneumatic
	If (above) = pneumatic; recommended PSI	Text box to fill in
	Rear wheel tread size	High or Low
	Front wheel tire type	Solid or Pneumatic
	Front wheel radius	3", 4", 5", 6"
	Wheelchair 'fit'	Right elbow angle measured, in degrees
	Number of years using this specific wheelchair	Less than 3 months,3-6 months, 6-12 months, 1-2 years, 2-3 years, 3-4 years, 4-5 years, 5-6 years, More than 6 years
	Quality of Life Basic Data Set	Three (3) item questionnaire on a 10 point Likert scale. Individual items will be scored.
	Basic Pain Data Set	5 question regarding pain.
	SCI-Spasticity Evaluation Tool	1 question regarding spasticity symptoms and transfers.
	The General Causality Orientations Scale (GCOS)	Twelve (12) item questionnaire on a 7 point Likert scale.

Criterion Fitness		
	Peak Aerobic Power	$W.kg^{-1}$
	Peak Oxygen Consumption	$ml.kg^{-1}.min^{-1}$
	Criterion Fitness - Continuous Recording	Participant's oxygen consumption and EKG will be recorded continuously throughout the test.
	Rate of Perceived Exertion (RPE)	Participants RPE will be recorded at the end of each 3 minute stage and upon completion of the test.
	Reason for test termination	Participant will be asked why he or she terminated the test.
	Could the participant have gone any longer into the test	Y or N, explain
Clinical Fitness Predictors		
	Resting Heart Rate	BPM
	Resting Blood Pressure	SBP/DBP mmHg
	6 Minute Push Test (6MPT)	Distance pushed measured (m)
	Participant stopped during test	Y or N, number of stops, time of each is noted
	Self-reported Mobility Disability Questionnaire	Four (4) item questionnaire on a 4 point Likert scale; individual items will be sub-scored and an overall score will be reported.
Balance		
	Modified Functional Reach Test	Participants will perform two (2) practice trials. Forward reach distance will be recorded for each of three (3) trials.
	Participants dominant arm	R or L
	Did tester note spasms pre/during or post-transfer?	Y or N
	Where	Tester notes where spasms appeared.
	Falls Concern Scale	Sixteen (16) item questionnaire on a 4 point Likert scale; individual items will be sub-scored and an overall score will be reported.
Neurological Impairment		
	ASIA Impairment evaluation - motor/sensory assessment from C2 to S3 (If available)	All individual sensory and motor items will be scored, all motor and sensory subscores computed, and overall over all classification computed
	Visual assessment of ability to perform various UE movements	Bilateral shoulder, elbow, wrist and hand active movements against gravity
Functional Independence		
	Spinal Cord Independence Measure (SCIM – III)	Seventeen (17) item self-report questionnaire; individual items will be sub-scored and an overall score will be reported.
	Spinal Cord Injury-Functional Index (SCI-FI) - Basic mobility domain	Six to twelve (6-12) item computer adapted testing (CAT) questionnaire in addition to a nine to eleven (9-11) item short form (SF) version; individual items will be sub-scored and an overall score will be reported. (See Appendix A: SCI-FI CAT and SF Item Banks)
	Spinal Cord Injury-Functional Index (SCI-FI) - Self-care domain	Six to twelve (6-12) item computer adapted testing (CAT) questionnaire in addition to a nine to eleven (9-

		11) item short form (SF) version; individual items will be sub-scored and an overall score will be reported. (See Appendix A: SCI-FI CAT and SF Item Banks)
	Spinal Cord Injury-Functional Index (SCI-FI) - Fine motor domain	Six to twelve (6-12) item computer adapted testing (CAT) questionnaire in addition to a nine to eleven (9-11) item short form (SF) version; individual items will be sub-scored and an overall score will be reported. (See Appendix A: SCI-FI CAT and SF Item Banks)
	Spinal Cord Injury-Functional Index (SCI-FI) - Wheelchair mobility domain	Six to twelve (6-12) item computer adapted testing (CAT) questionnaire in addition to a nine to eleven (9-11) item short form (SF) version; individual items will be sub-scored and an overall score will be reported. (See Appendix A: SCI-FI CAT and SF Item Banks)
	Difficulty completing various transfers to/from Wheelchair	Difficulty level measured on a five (5) point Likert scale.

Development of a clinical decision rule for classification of fitness impairments in SCI

Rachel Cowan

Miami Project to Cure Paralysis

March 9, 2017

Relevance of fitness to functional independence

Global objectives

1. Estimate clinically meaningful fitness gains

2. Estimate minimum fitness required to enable various functional activities

3. Develop a clinically feasible approach to generate clinically relevant estimates of fitness

4. Develop suggested 'treatment' recommendations to achieve functionally relevant fitness gains

Perform the largest study ever to examine the relationship between fitness and function

Study	Total (N)	TP (N)	PP (N)	M (N)	W(N)
Noreau et. al.	122	50	121	133	43
Hasima et. al. (start of rehab)	176	55	121	133	43
Hasima et. al. (1 yr post rehab)	133	36	97	96	37
Our study (target)	300	150	150	240	60
Our study (current)	92	35	57	72	20

Global objectives

1. Estimate clinically meaningful fitness gains

2. Estimate minimum fitness required to enable various functional activities

3. Develop a clinically feasible approach to generate clinically relevant estimates of fitness

4. Develop suggested 'treatment' recommendations to achieve functionally relevant fitness gains

Fitness and TRANSFER Independence

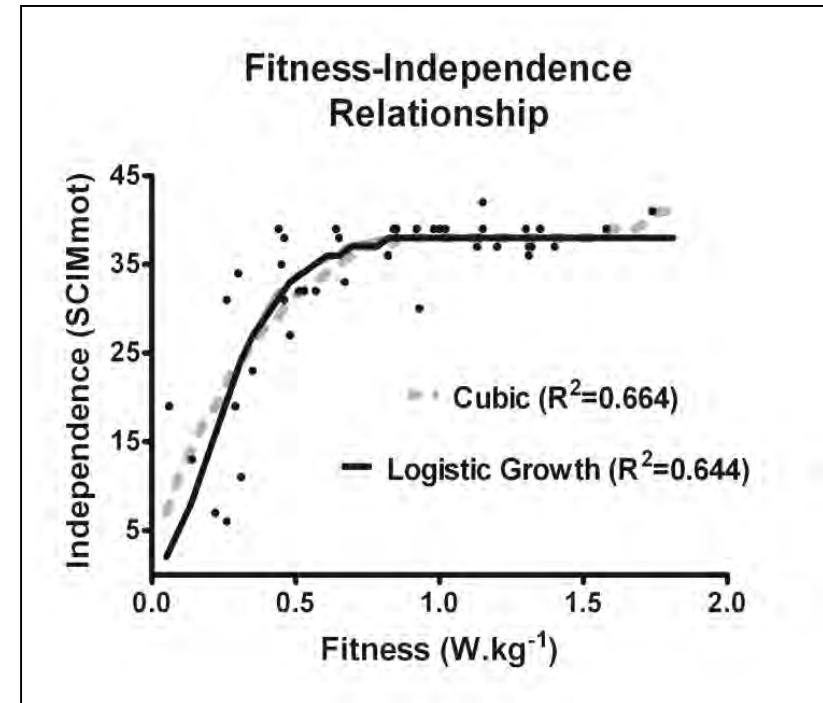# Fitness-Function Relationship (Preliminary Data)
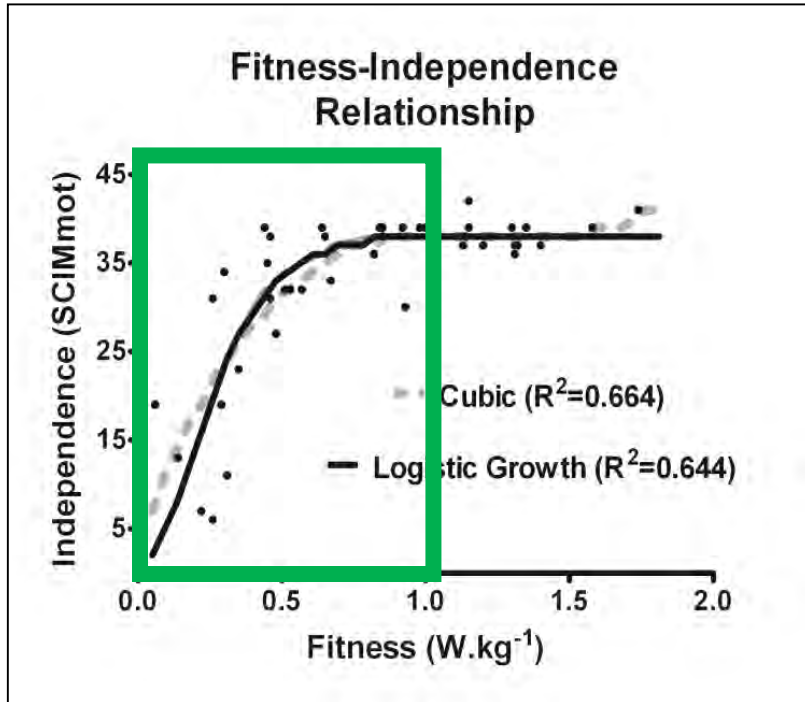
Figure 1. Fitness-Independence relationship. Preliminary data plotted (black dots) with cubic (grey dash line) and logistic growth curves (black solid line).

- Preliminary data indicate independent transfer fitness thresholds are:

  - 0.46 $W.kg^{-1}$ for bed to wheelchair

  - 0.64 $W.kg^{-1}$ for wheelchair to car transfers.

  - 0.80 $W.kg^{-1}$ for ground to wheelchair transfers

Project Overview

- DoD funded 3 center study

- Observational, cross-sectional

- N=300 target enrollment
  - Include if
    - Bilateral 3+ biceps (MMT) (3=full Active ROM against gravity)
    - Non-ambulatory with minimal voluntary LE motor

  - Exclude if
    - Contraindications to participation in maximal exercise

Current enrollment (02/28/2017)

N=97 consented, N=94 eligible, N=92 completed testing

- 78% men

- BMI: 25 kg/m2 (7)

- Current age: 40 yrs (14)

- Age at injury: 29 yrs (13)

- Injury duration: 11 yrs (9)

Current enrollment (02/28/2017)

N=97 consented, N=94 eligible, N=92 completed testing

Injury level, severity

- 62% self-report as thoracic/lumbar injury

- 40% sensory complete, motor complete   (A)
- 33% sensory incomplete, motor complete   (B)
- 02% sensory complete, motor incomplete   (C)
- 25% sensory incomplete, motor incomplete (C)

- 73% demonstrate bilateral elbow extension against gravity

Current enrollment (02/28/2017)

N=69 with bilateral elbow extension

Injury level, severity

- 84% self-report as thoracic/lumbar injury

- 44% sensory complete, motor complete (A)
- 29% sensory incomplete, motor complete (B)
- 03% sensory complete, motor incomplete (C)
- 24% sensory incomplete, motor incomplete (C)

Demographics

- 80% men

- Current age: 41 yrs (13)

- Age at injury: 29 yrs (12)

- Injury duration: 11 yrs (9)

- BMI: 25 kg/m2 (6)

Fitness and TRANSFER Independence

- Fitness level

- Transfer independence

Operational Fitness Definition & Criterion Measurement

- Graded exercise test to volitional exhaustion

- Arm Ergometry

- Peak power output normalized to body-weight

Figure 1. Fitness-Independence relationship. Preliminary data plotted (black dots) with cubic (grey dash line) and logistic growth curves (black solid line).

Measurement of Transfer Ability/Independence

- SCIM-III for self report

  - Mobility subscale
    - Q10 – Transfers from the bed to the wheelchair
      - I need total assistance
      - I need partial assistance, supervision or adaptive devices (e.g. sliding board)
      - I do not need any assistance or adaptive devices
      - I do not use wheelchair

    - Q17 – Transfers from the floor to the wheelchair
      - I need assistance
      - I do not need any assistance
      - I do not use a wheelchair

Measurement of Transfer Ability/Independence

- SCIM-III for self report

  - Mobility subscale
    - Q10 – Transfers from the bed to the wheelchair

      FALSE (N=15)
      - I need total assistance
      - I need partial assistance, supervision or adaptive devices (e.g. sliding board)

      TRUE (N=49)
      - I do not need any assistance or adaptive devices
      - I do not use wheelchair

    - Q17 – Transfers from the floor to the wheelchair

      FALSE (N=42)
      - I need assistance

      TRUE (N=24)
      - I do not need any assistance
      - I do not use a wheelchair

Fitness minimums for transfer independence

ROC curve analysis (sensitivity vs. specificity) (True positive vs. True negative)

Floor to Wheelchair
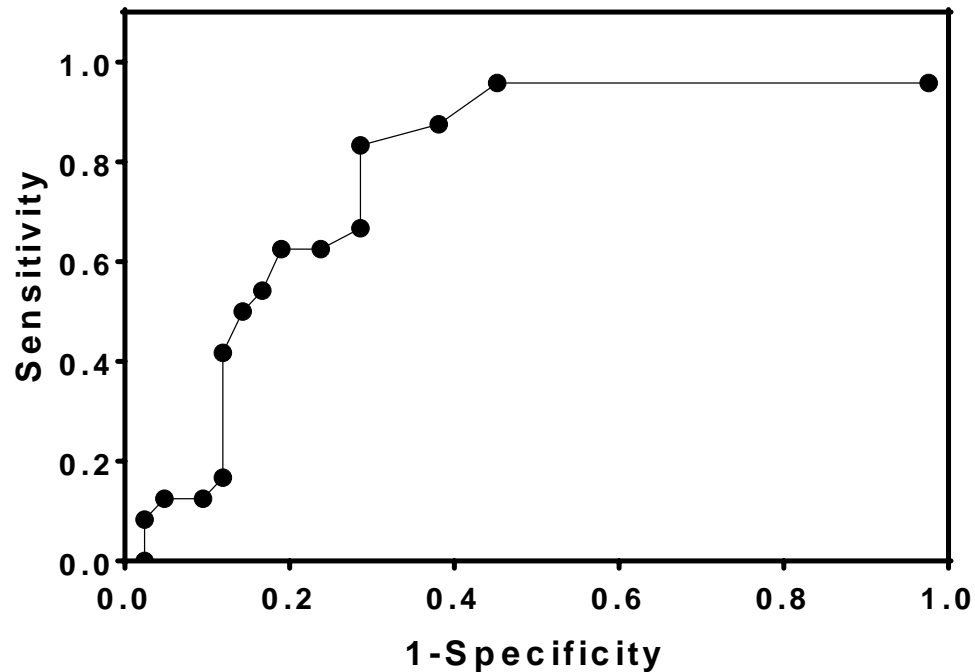
Bed to Wheelchair
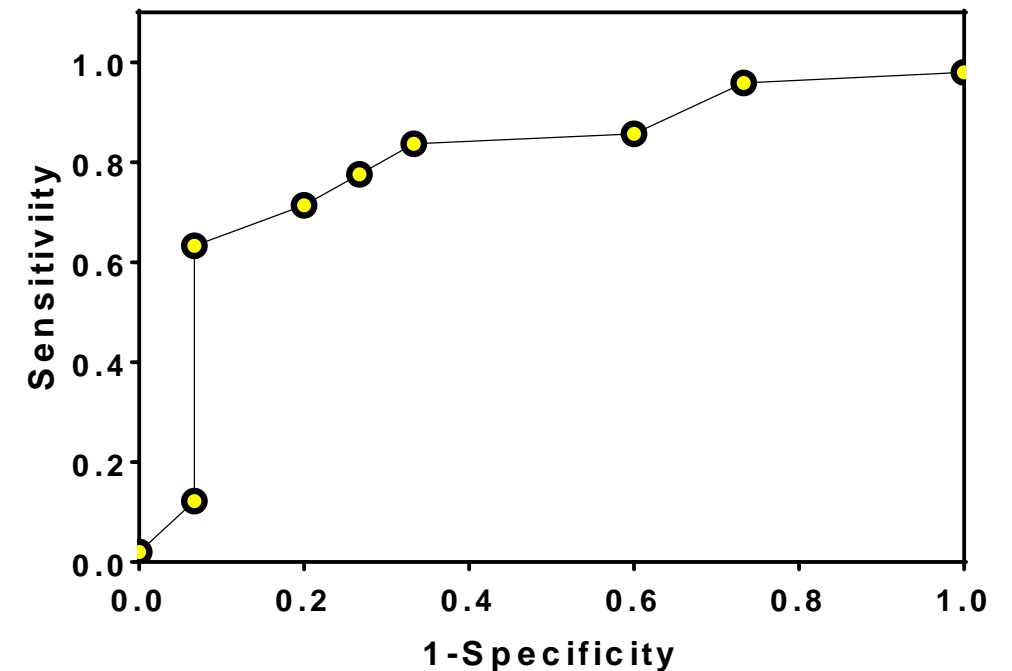
Fitness minimums for transfer independence

ROC curve analysis (sensitivity vs. 1-specificity) (True positive vs. 1-True negative)

Floor to Wheelchair

PO_{peak} = 0.83 W/kg

Sensitivity=83%

Specificity=71%

Bed to Wheelchair

PO_{peak} = 0.69 W/kg

Sensitivity=84%

Specificity=66%
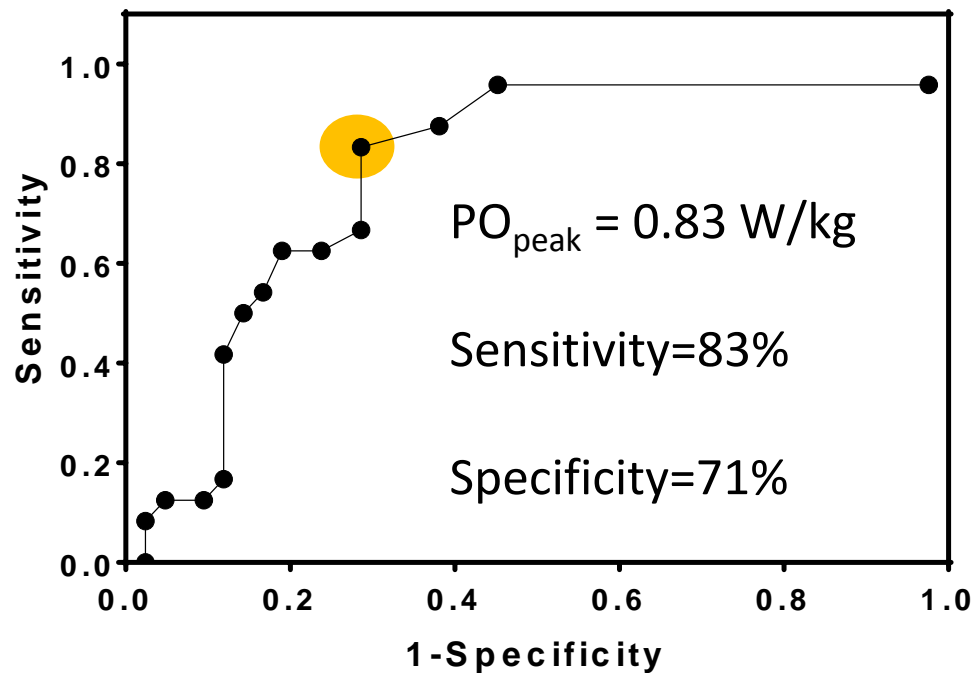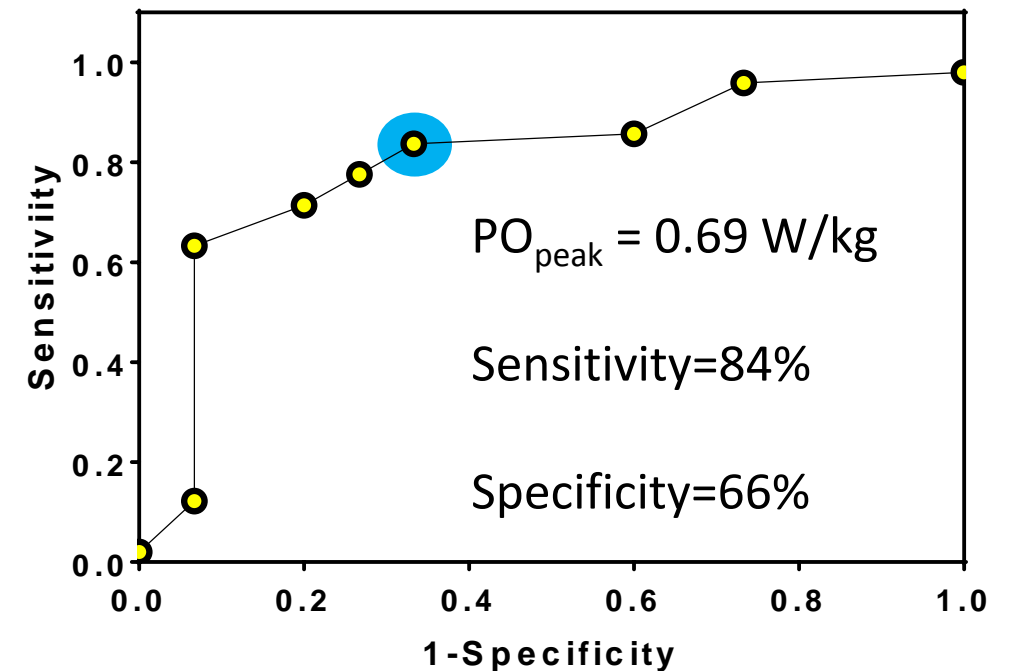
Fitness minimums for transfer independence

Pre-proposal data	Transfer	Preliminary results
0.46 W.kg^{-1}	**Bed to Wheelchair**	0.64 W.kg^{-1}
0.64 W.kg^{-1}	**Wheelchair to Car**	0.69 W.kg^{-1}
0.80 W.kg^{-1}	**Floor to Wheelchair**	0.83 W.kg^{-1}

Fitness minimums for transfer independence
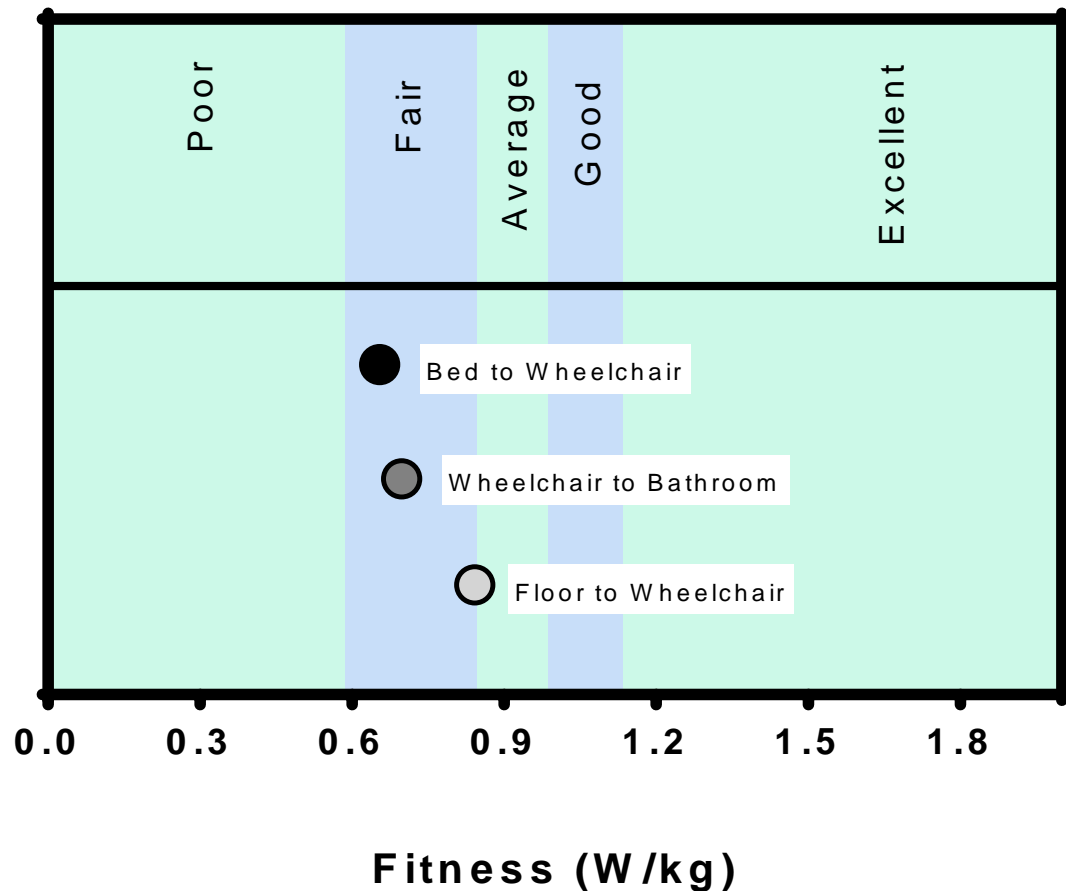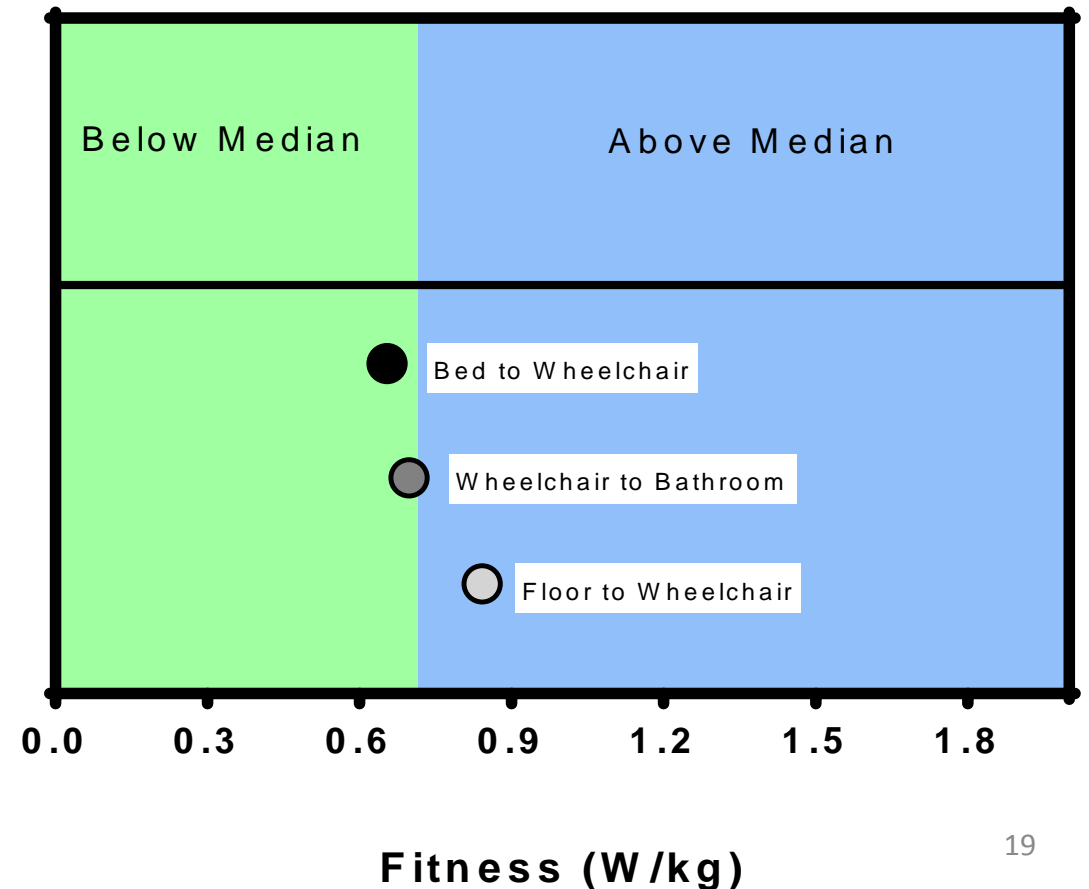
Global objectives

1. Estimate clinically meaningful fitness gains

2. Estimate minimum fitness required to enable various functional activities

3. Develop a clinically feasible approach to generate clinically relevant estimates of fitness

4. Develop suggested 'treatment' recommendations to achieve functionally relevant fitness gains

Global objectives

1. Estimate clinically meaningful fitness gains

2. Estimate minimum fitness required to enable various functional activities

3. Develop a clinically feasible approach to generate clinically relevant estimates of fitness

4. Develop suggested 'treatment' recommendations to achieve functionally relevant fitness gains

Develop a clinically feasible approach to generate clinically relevant estimates of fitness

- Requirement 1
  - Clinically feasible
    - Time burden ≤15 minutes
    - Low space & equipment burden

- Requirement 2
  - Clinically relevant

Clinically feasible fitness predictor variables

- Personal Characteristics
    1. Gender (M,F)
    2. Age at consent (yrs)
    3. Age at injury (yrs)
    4. Time since Injury (yrs)
    5. Height (cm)
    6. Weight (kg)
    7. BMI (kg/m^2)

- Injury Characteristics
    1. Current Wheelchair Use (manual, power, assist)
    2. Injury Completeness (sensory & motor)
    3. Bilateral elbow extension against gravity (Y,N)
    4. Pain (# of pain problems)
    5. Spasticity impact (on transfers)
    6. Fall concern (proxy for balance/trunk control)

- Physical Performance Measures
    1. 6 minute push test (distance travelled in 6 minutes)

- ADL independence & difficulties
    1. SCIM – 4 transfer questions (Bed, Bath, Car, Floor)
    2. 4 propulsion/transfer difficulty questions

Clinically feasible fitness predictor variables

- **Personal Characteristics**
  1. Gender (M,F)
  2. Age at consent (yrs)
  3. Age at injury (yrs)
  4. Time since Injury (yrs)
  5. Height (cm)
  6. Weight (kg)
  7. BMI (kg/m^2)

- **Injury Characteristics**
  1. Current Wheelchair Use (manual, power, assist)
  2. Injury Completeness (sensory & motor)
  3. Bilateral elbow extension against gravity (Y,N)
  4. Pain (# of pain problems)
  5. Spasticity impact (on transfers)
  6. Fall concern (proxy for balance/trunk control)

- **Physical Performance Measures**
  1. 6 minute push test (distance travelled in 6 minutes)

- **ADL independence & difficulties**
  1. SCIM – 4 transfer questions (Bed, Bath, Car, Floor)
  2. 4 propulsion/transfer difficulty questions

Making the fitness estimate clinically relevant

Making the fitness estimate clinically relevant

- Map the fitness estimates to codes required for billing and reporting

- G code modifiers
  - G code
    - functional domain groupings
    - E.g. mobility, body positioning, self-care

  - Modifiers
    - indicate "the severity/complexity of a functional limitation"
    - "reflect the beneficiary's percentage of functional impairment as determined by the clinician furnishing the therapy services"

Making the fitness estimate clinically relevant

% Impairment Limitation Restriction	G code modifier
At least **1%** but less than **20%** impaired, limited, or restricted	CI
At least 20% but less than 40% impaired, limited, or restricted	CJ
At least 40% but less than 60% impaired, limited, or restricted	CK
At least 60% but less than 80% impaired, limited, or restricted	CL
At least 80% but less than 100% impaired, limited, or restricted	CM
100% impaired, limited, or restricted	CN

Clinically relevant – proposed approach #1

- Map 80% prediction interval against impairment categories

- 7 – Predictors
  - Weight
  - 6MPT distance
  - Fall Concern Questionnaire total score
  - 2 SCIM questions
 - 1 question re: transfer difficulty

- Adjusted R^2=0.69

Clinically relevant – proposed approach #2

- Present probability for each category

- Predictors
  - 6MPT distance
  - More can be added

- Example: patient
  - 6MPTD = 324 m

probability of % impairment group given 6MPT of 250-349m

Clinically relevant – proposed approach #2
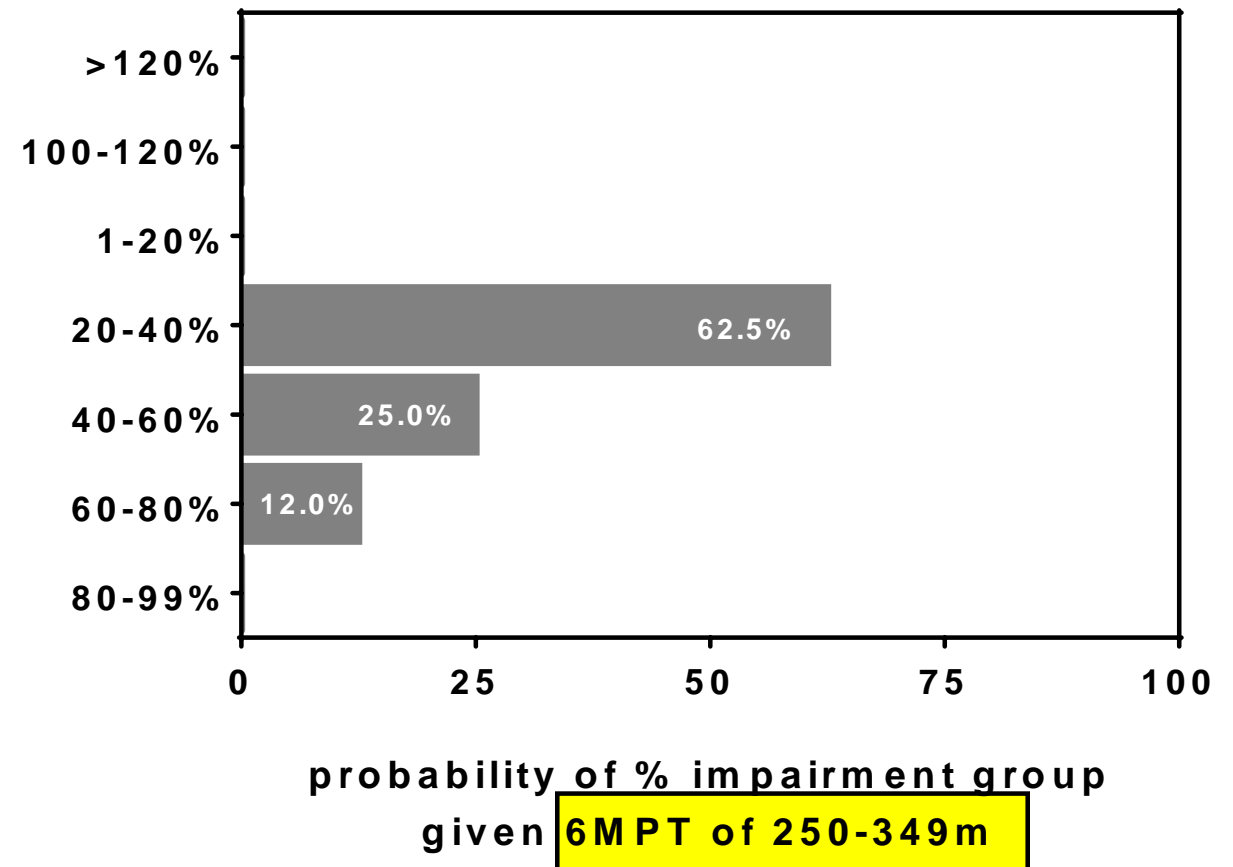
- Present probability for each category

- Predictors
  - 6MPT distance
  - More can be added

- Example: patient
  - 6MPTD = 424 m
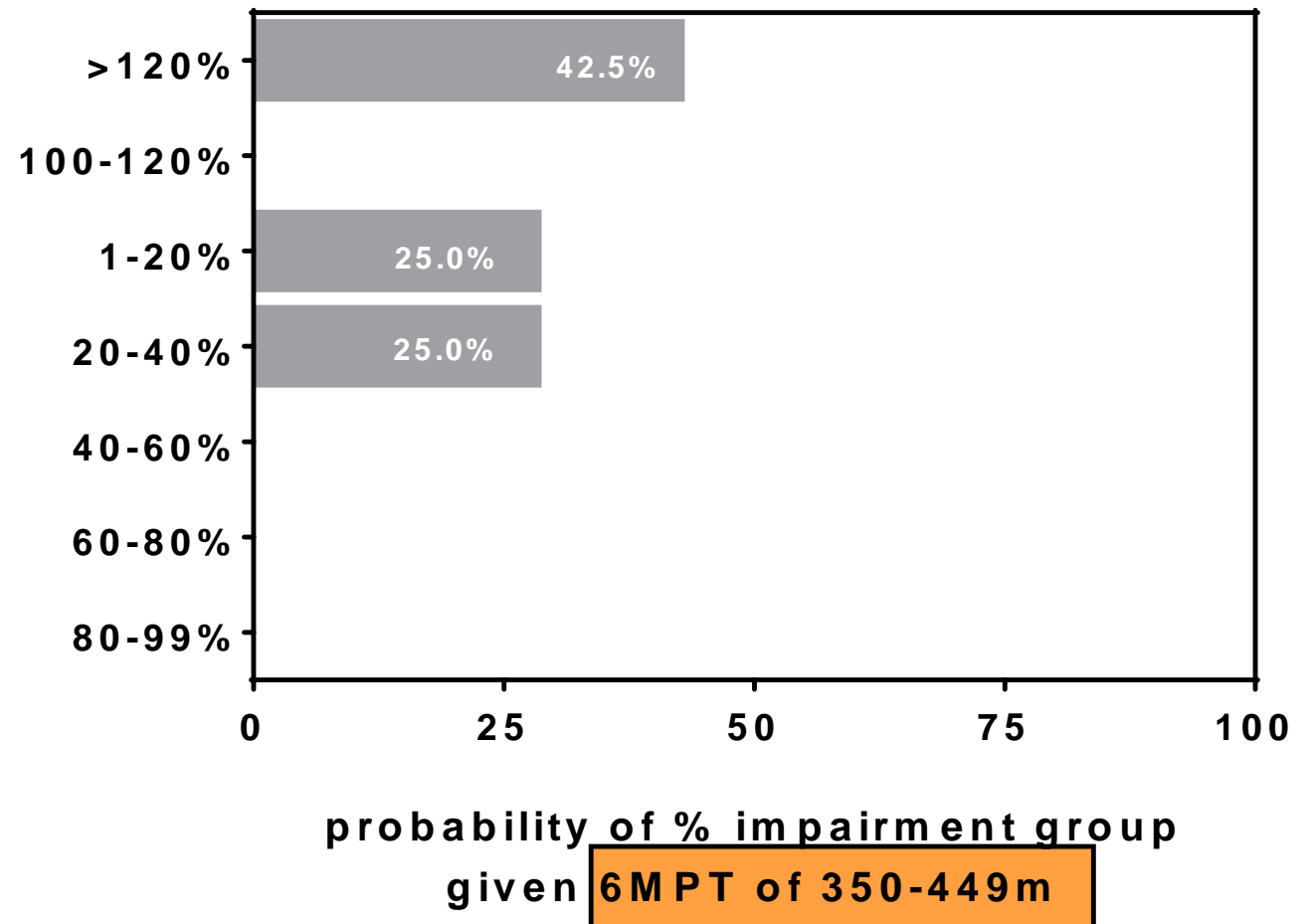
probability of % impairment group given 6MPT of 350-449m

Global objectives

1. Estimate clinically meaningful fitness gains

2. Estimate minimum fitness required to enable various functional activities

3. Develop a clinically feasible approach to generate clinically relevant estimates of fitness

4. Develop suggested 'treatment' recommendations to achieve functionally relevant fitness gains

Moving forward

- 18 months of data collection remaining

- Defining next project

- Include SCI <6 months post

- Develop treatment suggestion

- Support
  - DoD
  - Personnel
    - MIA
      - J. Maher
      - C. Fitzmaurice
      - A. Palermo
      - J. Tibbett
      - E. Widerstrom-Noga
      - K. Anderson
    - NRH
      - S. Groah
      - I. Ljungberg
      - E. Tinsley
      - A. Garver
    - GMU
      - A. Gucicone
      - R. Keyser
      - D. Murray

SCI fitness categories (Popeak W/kg)

		5th Quintile (0-20%)	20%-40%	40%-60%	60%-80%	1st Quintile (80%-100%)
Men	PP (N=81)	<0.58	0.58-0.84	0.85-0.98	0.99-1.13	>1.13
	TP (N=42)	<0.06	0.06-0.13	0.14-0.26	0.27-0.48	>0.48
		Median	Range			
Women	PP (N=15)	0.71	0.25-1.27			
	TP (N=6)	0.19	0.00 – 0.63			

Current enrollment (02/28/2017)

N=69 with bilateral elbow extension

Pain (Basic Data set)	**Spasticity (SCI-SET)**

Pain (Basic Data set)

- 77% report pain in last 7 days

- Number of pain problems (N=69)
  - 0:   23%
  - 1:   15%
  - 2:   28%
  - 3:   16%
  - 4:   04%
  - 5+: 12%

Spasticity (SCI-SET)

Impact of spasticity on transfers

- 39% No impact

- 45% problematic

- 13% helpful

- Are people with SCI within 10lbs of their weight?

- Increase in PO with Exercise interventions

- Decrease in weight achievable with DPP program

Upper Extremity Evaluation

Motion	C5	C6	C7	C8	T1
Shoulder Abduction	X	X			
Shoulder Flexion	X	X			
Shoulder Extension	X	X	X		
Elbow Flexion	X	X			
Elbow Extension		X	X	X	
Wrist Extension	X	X			
Wrist Flexion		X	X	X	
Palm down, fingers & thumb extended & abducted			X	X	X
Palm down, fingers flexed & abducted, thumb flexed & adducted around fingers			X	X	X

Upper Extremity Evaluation - Proposed
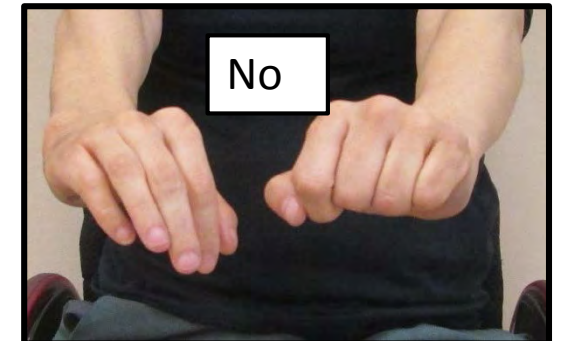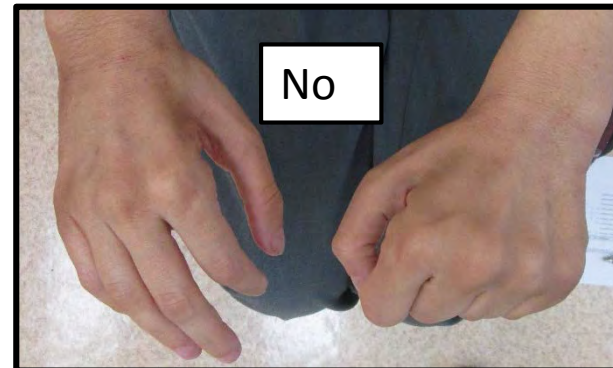
Elbow Flexion   (C5, C6)

Elbow Extension (C7, C8)
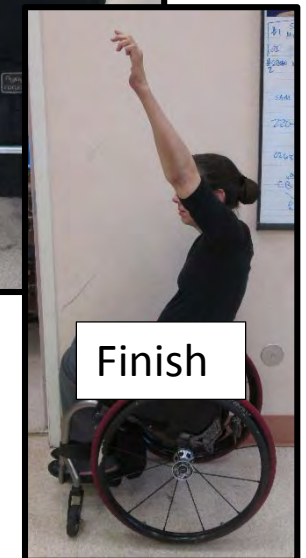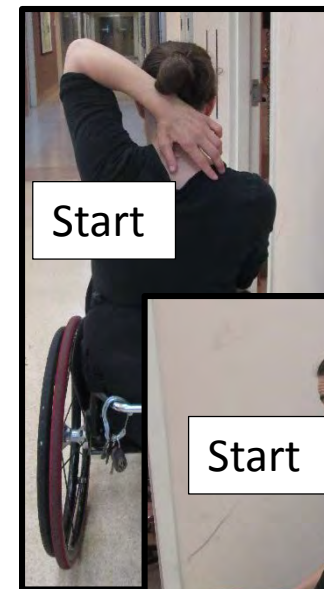
Upper Extremity Evaluation - Proposed

Hand Closed, Palm up, fingers flexed & abducted, thumb flexed & adducted around fingers (C8/T1)

- Identify the minimum fitness level required to support transfer independence (i.e. no human help required)
  - Ex ROC curve to identify false vs true positive
  - http://gim.unmc.edu/dxtests/roc2.htm
- Identify the relationship between perceived difficulty of transfers and fitness
  - What is the fitness level required to achieve 'no difficulty at all'
- Develop an algorithm to estimate an individual's 'fitness' level within 0.05 w/kg accuracy

Objective of this development project

- Define functionally relevant fitness 'thresholds'
  - i.e. – minimum fitness level required to support independence in specific ADL

- Identify a set of 'clinical' measures that predict an individual's fitness relative to each 'threshold'

- Develop 'output' to support and inform treatment decisions/justifications

- DOST – 2014
  - 5 weeks of daily training
    - Resistance = +15.75 FIM points (N=10)
    - Arm ergometry = +20.78 FIM points (N=9)

VO$_2$ OFF-KINETICS FOLLWING EXHAUSTIVE UPPER BODY EXERCISE TEST IN MOTOR COMPLETE SPINAL CORD INJURY

Donal Murray[1], Rachel E. Cowan[2] and Randall E. Keyser, FACSM[1]

[1]George Mason University, Fairfax, VA, USA. [2]University of Miami, Miami, FL, USA.

Introduction: People with spinal cord injury (SCI) have impaired autonomic control below the level of the lesion. This could lead to impaired recovery following vigorous physical activity. **Purpose:** To compare VO$_2$ off-kinetics following a maximal cardiopulmonary exercise test (CPET) in motor complete SCI and un-injured healthy individuals. **Methods:** Subjects were 13 patients with SCI (age: 39.1 ± 10.9 years) and 10 healthy controls (CON group; age: 30.5 ± 5.3 years). All subjects performed an arm ergometer cardiopulmonary exercise test (CPET) to volitional exhaustion followed by a 10-minute passive recovery. VO$_2$ off-kinetics was determined using a mono-exponential model in which a time constant (τ_{off}) was calculated and amplitude of change in VO$_2$ (AMP) was measured over the recovery period. Student's t-tests were used to compare SCI vs CON group means and Pearson product moment correlation coefficients were used to assess the relationships amongst VO$_{2peak}$ and the VO$_2$ off-kinetic variables. **Results:** Compared to CON, SCI had significantly longer τ_{off} (83.4 ± 34.7 vs.54.7 ± 10.2seconds, p=0.021). A significant difference in AMP was not seen between the subjects with SCI and CON (0.85 ± 0.57 vs.1.31 ± 0.48L/min, p=0.054) however the ratio of AMP/τ_{off} was significantly smaller in the group with SCI than in CON (0.0126 ± 0.0108 vs. 0.0243 ± 0.008L/min/sec, p=0.011). VO$_{2peak}$ and τ_{off} were inversely related (r=-0.524, p=0.01). **Conclusions:** Potentially explained by the time taken to replenish muscle ATP stores and lactate clearance, VO$_2$ off-kinetics is one measure of cardiorespiratory fitness. Despite an observable decline in AMP, the prolonged VO$_2$ off-kinetics suggested that cardiorespiratory fitness was impaired in these subjects with motor complete SCI.

Association of Six-Minute Push Test Distance and Measures of Cardiorespiratory Fitness In Individuals With Spinal Cord Injury.

Baian Baattaiah[1], Donal Murry[1], Rachel E. Cowan[2] and Randall E. Keyser FACSM[1].
[1]George Mason University, Fairfax, VA, USA., [2]University of Miami, Miami, FL, USA.

Introduction: The 6-minute push test is often used to estimate cardiorespiratory fitness in people who have spinal cord injury (SCI). **Purpose:** To characterize the relationship between 6-minute push distance (6MPD) and measures of cardiorespiratory function obtained during cardiopulmonary exercise tests (CPET) in patients with SCI. **Methods:** Subjects were 13 motor complete SCI patients with no functional use of their lower extremities (Age: 33.5 ± 10.9 years: BMI: $25.6 \pm 3.5 kg/m^2$). Each subject performed a cardiopulmonary exercise test (CPET) to volitional exhaustion using a Monark arm ergometer during which pulmonary gas exchange variables were measured and perceived exertion was rated. 6MPD was recorded as the total distance covered while propelling wheelchair in a 30-meter corridor over 6-minutes. Pearson product moment correlation coefficients were used to assess the relationship between all study variables. **Results:** 6MPD was 526.9 ± 134.4 m, VO_{2peak} was 18.3 ± 8.2 ml/kg/min and RER was 1.12 ± 0.15. CPET duration averaged 412.5 ± 185.9 seconds, peak workload was 73.6 ± 43.4 Watts and rate of perceived exertion achieved at the end of exercise was 6.8 ± 2.6. There 6MPD correlated significantly with VO_{2peak} ($=0.62$; $P=0.023$), RER ($r=0.74$; $P=0.004$), peak exercise time ($r=0.75$; $P=0.003$), peak workload ($r=0.68$; $P=0.01$), rate of perceived exertion ($r=0.73$; $=0.005$). **Conclusion:** CPET is currently accepted as the gold standard for measuring cardiorespiratory fitness. The strong correlation between cardiorespiratory fitness measured by CPET and 6MPD suggested that 6MPD might be an adequate field test for measuring cardiorespiratory fitness in people who have SCI.